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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Patricia Harris
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ENFORCEMENT COMMITTEE MEETING

March 9, 2005
9:30 a.m. – 12:30 p.m.

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019
(818) 843-6000

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER 9:30 a.m.

A. Discussion Regarding the Importation of Prescription Drugs

B. Request from University of San Diego (UCSD) Medical Center for Waiver of California Code of Regulations, title 16, section 1717(e) to Use an Automated Dispensing Device for Refill Prescriptions at its Outpatient Pharmacy

C. Letter from Jeffrey A. Moss, Attorney for the Pharmacy Defense Fund Related to the Waiver of California Code of Regulations, title 16, sec. 1717(e) – Use of an Automated Dispensing Device

D. Centers for Medicare and Medicaid Services (CMS) Implementation of the Medicare Drug Improvement and Modernization Action (MMA) of 2003 – Proposed Electronic Prescribing Standards National Association of Boards of Pharmacy (NABP) Request for a Response to the Question: "Do you think that the security and privacy provisions for the electronic transmission or e-prescribing of non-controlled substances and C-III to C-V controlled substances prescription should be equivalent and more stringent requirements in place for C-II controlled substances prescriptions only?"

E. Information on the Prescribing Authority for Naturopathic Doctors

F. Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Prescribing and Dispensing Controlled Substance Prescriptions as of January 1, 2005

G. Implementation of SB 1307 (Senator Figueroa) Relating to Wholesalers
   - Presentation at the April Board Meeting by the Acerity Corporation on Its Technological Solution to Detect Counterfeits
   - NABP Task Force to Develop Recommendations for Electronic Pedigree Requirements

H. Next Enforcement Committee Meeting Date: June 22, 2005 in Sacramento

I. Adjournment **12:30 p.m.**

Committee materials will be available on the board's website by March 2, 2005

AGENDA ITEM A

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: February 25, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Importation of Prescription Drugs**

This is a standing agenda item for the meetings of the Board and the Enforcement Committee. Attached are various articles that have appeared since the last board meeting. Also included is a letter from the Department of Health and Human Services to the Attorney General of Rhode Island regarding a recently enacted law in Rhode Island that authorizes the Rhode Island Board of Pharmacy to license Canadian pharmacies.

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State Watch | Washington State House Approves Prescription Drug Reimportation Legislation
[Feb 22, 2005]

The Washington state House on Wednesday voted 56-42 to approve a bill that would encourage state employees to purchase prescription drugs from Canadian pharmacies, the AP/Spokane *Spokesman Review* reports (Ammons, Spokane *Spokesman-Review*, 2/17). The legislation, sponsored by state Rep. Geoff Simpson (D), would offer financial incentives, such as exempted or discounted copayments -- to about 143,000 state employees, dependents and retirees enrolled in the Uniform Medical Plan who purchase prescription drugs from Canadian pharmacies. In addition, the bill would provide legislative approval for a state Web site established last year that helps residents purchase prescription drugs from online Canadian pharmacies, provided that FDA approves the practice. Simpson said that the state could save $10 million annually under the bill. Simpson said, "I don't know how many millions and millions of dollars we have allowed pharmaceutical companies to gouge citizens, but I think it's time to put an end to it." The legislation moves to the state Senate for consideration.

Additional Legislation
Two other bills that would authorize the state to inspect and license Canadian pharmacies and wholesalers remain under consideration in the state House and Senate. One bill would require an FDA waiver, and the other bill would require cooperation from Canadian health officials, the *Seattle Times* reports. Provisions in the bills also could make the state liable in the event that residents experience injuries as a result of reimported prescription drugs. State Rep. Shay Schual-Berke (D), who sponsored one of the bills, said, "It is very definitely about sending a message, about standing up for Washingtonians. If and when the Bush administration relents and allows a waiver, we

are set to go." However, William Hubbard, FDA associate commissioner for policy and planning, said, "We don't have any waiver authority" to approve reimportation. He added, "Drugs have to be cleared before they come into the country. The FDA was created 100 years ago for that reason" (Perry, *Seattle Times*, 2/17).

DRUG TOPICS THE ONLINE NEWSMAGAZINE FOR PHARMACISTS

Saturday, Feb 26, 2005

Canadian mail-order pharmacy in turmoil

Feb 7, 2005
By: Carol Ukens
Drug Topics

Already hurt by a drug company clampdown on supplies and a falling U.S. dollar that have raised prices to American consumers, Canadian mail-order pharmacies are bracing for a federal regulatory crackdown that they claim will force them to set up shop on friendlier shores.

Canada Health Minister Ujjal Dosanjh has proposed three regulatory changes to protect the country's domestic drug supply and pricing structure. He has proposed making it illegal for Canadian doctors to co-sign foreign scripts, prohibiting noncitizens from acquiring drugs unless they come to Canada and are physically examined by a Canadian doctor, and prohibiting certain drugs in short supply from being dispensed to foreigners.

Dosanjh was expected to deliver his final recommendations to the cabinet late last month. By using the order-in-council process, the government does not have to consult with the House of Commons and members of the opposition. And a requirement for a 75-day stakeholder consultation period could be waived.

All of the health minister's proposed regulations "would be lethal for the mail-order pharmacy sector in Canada and mean the loss of 4,000 jobs," said David MacKay, executive director, Canadian International Pharmacy Association (CIPA). "If they are implemented, hundreds of thousands of Americans could be thrown into therapeutic crisis."

Most Canadian mail-order pharmacies have drafted contingency plans to move their operations if the federal government follows through with its regulatory plans. "We have already begun to diversify our operations as a result of the drug supply restriction schemes of seven manufacturers," MacKay told *Drug Topics*.

"All of the CIPA pharmacies have contingency plans for foreign fulfillment—primarily in the European Union," MacKay continued. "Fulfillment would occur overseas with some aspects of the operations such as call centers remaining in Canada. Some will be partnerships; some will be operations owned by the original Canadian pharmacy. Distance-based healthcare delivery is a global trend that cannot be stifled. Instead of regulating a small pipeline from Canada, this will become a worldwide distribution model that involves more than 20 countries without sacrificing safety."

It's not clear where the Canadian regulations will leave the states that have set up drug importation plans. Also up in the air is Rhode Island's new law authorizing the state pharmacy board to license Canadian mail-order pharmacies. The new law, which expires on Dec. 31, 2007, was enacted last summer without the signature of the governor, who was leery of openly flouting U.S. drug laws.

A legal challenge to the new licensure law has been ruled out by the Rhode Island Pharmacists Association, said executive director Jack Hutson. He added that communications with the Food & Drug Administration indicated the agency would send a letter to the state attorney general saying importation is illegal.

"Everyone already knows it's illegal," Hutson said. "The reality is that proponents of drug importation wear its illegality like a badge of honor. The pharmacy board rejected the licensure regulations that were proposed. The department of health did very little work on promulgating the regulations because it fully expected to be enjoined in a lawsuit. That's not happening. This thing is going through."

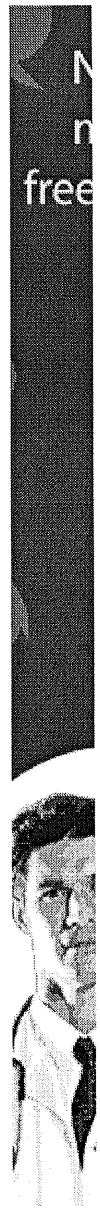
The state pharmacy board did not respond to requests for comment on the new law or how it plans to implement it. However, there have been inquiries about the licensure regulations that appear to require only that pharmacies hold a valid Canadian license, said Carmen Catizone, executive director, National Association of Boards of Pharmacy.

The Rhode Island situation is worrisome because if it is not legally knocked down, other states will opt for licensure of Canadian pharmacies, said Catizone. "Our concern is that legislators and governors are bypassing the pharmacy board and, second, where does it end?" he said. "I don't put much credence in the Canadian pharmacies' threats to move to Great Britain because they're already operating there anyway. It almost seems as if it won't end unless the FDA takes legal action against a state or municipality or we simply create global pharmacies."

About the Author

Carol Ukens

About Carol Ukens
See more articles by Carol Ukens



ABC NEWS ORIGINAL REPORT**originalreport**

Drug Companies Crack Down on Canadian Internet Pharmacies

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Blacklisting Moves Some Companies Overseas, May Compromise Drug Safety

Blacklisting Moves Some Companies Overseas, May Compromise Drug Safety

By JOHN McKENZIE

ABCNEWS

WINNIPEG, Manitoba, Feb. 7, 2005 — Trying to circumvent soaring prescription drug prices in the United States, an estimated 2 million Americans buy their medications from Internet pharmacies in Canada, which employs government price controls. Some major pharmaceutical companies are now aggressively trying to stop the cross-border sales.

The biggest pharmacy in all of Canada — where many of the Internet pharmacies are based — does not sell one pill to a Canadian.

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"Our clientele is 100 percent American and we dispense over 3,000 prescriptions per day," said Bob Fraser, lead pharmacist for the Web site CanadaDrugs.com.

At least 80 Internet pharmacies in Canada cater to Americans — selling Fosomax for osteoporosis, Paxil and Effexor for depression, Nexium for heartburn, Lipitor for high cholesterol — all for 30 percent to 40 percent cheaper than U.S. prices.

What started out five years ago with one Canadian pharmacist selling Nicorette gum to Americans via the online auction site eBay has turned into an $800 million-a-year business.

Blacklisting Internet Pharmacies

That business is threatening the drug industry's profits in the United States, and several drug makers are now blacklisting the online pharmacies.

Pharmaceutical companies including Pfizer, Wyeth and Eli Lilly have all cut off supplies to any Internet pharmacy selling drugs to Americans.

Documents obtained by ABC News show how Merck's Canadian subsidiary — Merck Frosst — approached drug wholesalers that supply the Internet pharmacies. The company demanded " a written statement that you have not sold and will not sell Merck Frosst's drug products to entities which are selling, or enabling for sale, such products into the United States," according to one document.

"I believe it is to drive us out of business because it is a complete cutoff," said Dave MacKay, chief executive of the Canadian International Pharmacy Association.

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1. 2. NEXT»

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Drug firms squeeze Canadian imports

They seek to bar resales to U.S.

By Judith Graham
Tribune staff reporter
Published January 30, 2005

As state and federal lawmakers debate proposals to help Americans buy cheap drugs from Canada, the supply of drugs available to Americans from their northern neighbor is rapidly drying up.

Seven major drug companies are now declining to sell their products to Canadian pharmacies that send medications south.

The prohibition affects almost one-third of the drugs previously available through Canada's online pharmacies, according to David MacKay, executive director of the Canadian International Pharmacy Association.

Americans haven't felt the shortages yet because Canadian Internet pharmacies have stocked up on products and cobbled together arrangements to purchase medications from colleagues. But those undercover arrangements are fragile at best, and no one expects them to last much longer.

"I think consumers will really start feeling the impact in the next two to three weeks," said Lee Graczyk, legislative director of the Minnesota Senior Federation, which runs a Canada drug-buying program for 30,000 members.

American consumers probably won't be able to get brand-name drugs from their usual Canada sources, he said, and will be forced instead to purchase generics from Canada, buy medications from overseas, pay more for the drugs in the U.S., or simply go without.

Entire classes of medications are being affected. For instance, two leading anti-cholesterol therapies, Lipitor and Zocor (made by Pfizer Inc. and Merck & Co., respectively) are now on drug companies' "don't sell" list for Canadian online pharmacies, along with a third cholesterol-buster, Mevacor (another Merck product).

About 2 million Americans seeking relief from soaring drug prices buy more than $700 millic discounted prescription medications from Canada each year. The medications cost up to 50 north of the border because Canada's government negotiates price breaks with pharmaceut companies. Most countries impose price controls on drugs, but the U.S. doesn't.

Two weeks ago, Merck & Co. became the latest pharmaceutical company to close its drug p Canada's online pharmacies. Among Merck's top-selling drugs are Fosamax, a treatment fo osteoporosis that is thought to be the best-selling imported medication from Canada.

"We ask that you confirm to us that you are not selling, and will not in the future sell, directly to ... parties who are selling Merck drug products into the U.S.," the company's Canadian su wrote in a Jan. 14 letter to an undisclosed number of pharmacies. Those who don't sign the won't receive Merck's medications, according to Tony Plohorous, a company spokesman.

Other firms that have cracked down on Canada's online pharmacies include GlaxoSmithKlir Eli Lilly and Co., Aventis, Astra Zeneca, and Wyeth Pharmaceutical.

Five Republican and three Democratic lawmakers--including Illinois Democrat Rahm Emanu importation issue on Congress' agenda again last week with a new bill that would allow Ame drugs from Canada and other countries. A similar proposal, bitterly opposed by the drug ind last year. Initiatives aimed at facilitating imports also are being considered in several states, Washington and Connecticut.

Illinois launched a program, I-SaveRx, that allowed residents to buy drugs from Canada, Ire United Kingdom last year.

Meanwhile, the squeeze on medication is contributing to a major shift in the online drug bus bid to keep operations going, Canadian Internet pharmacies are hatching plans to move to t Kingdom, forging partnerships or buying interests in European druggists, and developing ne can supply medications across the world, officials say.

"We have pharmacies now in almost 30 countries ready to ship to U.S. consumers," said Da Jorgenson, owner of Canadameds.com, one of Canada's largest Internet pharmacies.

A new generation of online pharmacies is being developed in the United Kingdom to step in if Canadian pharmacies become unable to serve U.S. customers, experts say. Although an between that country and the U.S., there are no language barriers, and quick delivery would problem.

Pharmacies' polls indicate that customers are ready to consider alternatives.

"About 99 percent of our customers tell us they'd accept product from the U.K.; 97 percent f way about Australia and New Zealand," said Andy Troszok, president of Extended Care Pha Internet drug outlet in Calgary, Alberta. The firm has plans to establish European operations summer, he said.

Drug companies' actions aren't the only threat to Canada's online drug outlets. The federal g in Ottawa has indicated it likely will impose strict new regulations. Options under considerati requiring Canadian physicians to examine American customers, mandating that customers f Canada to buy medications or putting drugs on a do-not-sell list if shortages seem imminent

While reports this month suggested government action was imminent, Ken Polk, a spokesm Canada's Health Ministry, says: "the department is still working up recommendations. There frame on this."

Seven U.S. governors, including Illinois' Rod Blagojevich, have asked Canadian Prime Minis Martin for a meeting and requested that he allow Canadian drug exports to the U.S. to conti Canada's government is reviewing the request, Polk said, and is "happy to sit down with the but a resolution to the issue of high drug prices needs to be found in the U.S., not in Canada

Meanwhile, Illinois is beginning to take action against drug companies shutting off supplies f pharmacies. The state has reduced business with the companies by $1 million so far and pl

remove many of their drugs from state-approved formularies in the year ahead, said Abby O spokeswoman for Blagojevich.

In Minnesota, Atty. Gen. Mike Hatch is investigating industry practices and plans to widen a against drug companies in the coming year.

Hatch sued the first drug company to cut off supplies to Canada's Internet pharmacies, Gla last summer. In a telephone interview, he said he planned to extend that lawsuit this year to Lilly, Merck, Aventis, Astra Zeneca, and Wyeth, which have followed GlaxoSmithKline.

"A company on its own may decide who they want to sell to and who they want to boycott," "But if a company collaborates with other companies [in making these decisions], that's a vi antitrust laws."

Hatch says he has documents from GlaxoSmithKline substantiating a "conspiracy" among c companies to stop selling drugs to Canadian pharmacies serving U.S. customers. The docu sealed, and Hatch is petitioning the Minnesota Supreme Court to lift a court order that preve contents from being disclosed.

Nancy Pekarek, a Glaxo-SmithKline spokesman, said the firm acted independently and insi antitrust allegations have no merit.

In any event, U.S. drug companies now face an unprecedented challenge: a growing global discounted drugs, being pushed by some Canadian pharmacies, that will allow Americans t medications via the Internet.

A look at Canadameds.com's Web site shows what the future holds. Its home page announ "Worldwide supplier of discount medications. ... Not just from Canada anymore. You choose and you choose the savings."

Search for price information on a popular drug such as Prozac, an antidepressant made by entries pop up showing the cost of drug orders from the U.K. ($145.87 for 90 capsules), Aus ($208.94 for 84 capsules), Israel ($69.72 for 56 capsules), Chile ($172.65 for 84 capsules) a ($206.11 for 90 capsules).

But how comparable are these drugs' doses to those available in the U.S.? How safe are pr pharmacies that dispense them? How reliable is government oversight in these nations?

These are issues raised by Jeff Trewhitt, a spokesman for Pharmaceutical Research and M of America, the industry's major trade group, who said, "Taking imported medicines can be Russian roulette."

Prescription Drug Importation Update: Oregon Proposes Novel Program

Importing prescription drugs from Canada and other countries has been a hot-button issue throughout 2004 and shows no signs of ceasing in 2005. Even though the United States Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) had, as of press time, not changed their prohibition on reimportation due to public safety concerns, an increasing number of state and local officials across the country are establishing avenues through which their citizens may purchase prescription medications from outside the US. This proliferation of government-sponsored plans for providing access to drugs from outside the US raises important public safety issues for state boards of pharmacy.

In the August 2004 *NABP Newsletter*, the Association noted that 13 states and several cities were in the planning stages of or had already established programs facilitating their citizens' access to imported drugs. Since that time, more municipalities have entered the arena. The governors, mayors, and other politicians involved in these programs cite a sense of urgency in providing citizens with access to affordable medications, and frustration with lawmakers and regulators for not legalizing the process.

In response to these actions, regulatory officials continue to raise concerns over patient safety. "[HHS] Secretary [Tommy G.] Thompson has not yet been able to certify that importation would (1) pose no additional risk to the public health and safety and (2) result in a significant reduction in the cost of drugs to the American consumer," FDA noted in an August 2004 press release. HHS, meanwhile, through its Task Force on Drug Importation, is attempting to determine whether or not, and under what circumstances, drug importation might be conducted safely. As of press time, publication of the Task Force's findings is still scheduled to be released in December 2004. (See "HHS Task Force Studies Illegal Drug Importation" in the July 2004 *NABP Newsletter.*)

The HHS Task Force report will also address the likely consequences that legalizing prescription drug importation would have for US consumers' health, medical costs, and development of new medicines. The Congressional Budget Office (CBO) has already issued a brief analysis of the cost-reduction issue in April 2004; it concluded that permitting nationwide drug importation from Canada would produce "a negligible reduction in drug spending," largely because "unique aspects of the prescription drug market would limit the additional volume of prescription drugs reaching the United States." The report noted, "[W]hile an individual can fill a prescription in another country and realize savings reflecting the full difference in price, the same would not be true for the health care system overall." The CBO assumed that drug manufacturers would take measures to restrict supplies to Canada in the case that

importation to the US were legalized; it did not address the possible results if Congress outlawed such activities by manufacturers.

While those in charge of safeguarding the public health and safety examine and debate the importation issue, many individual states continue to forge ahead with their plans to help US consumers import prescription drugs. Most of these plans, like Illinois', have been established despite federal regulations in the matter. However, a few plans continue to attempt to work within the system: Vermont filing a lawsuit against FDA to force the creation of importation guidelines, for example, and Oregon working closely with its board of pharmacy to develop a unique pilot program proposal.

Typical State Activities

Some typical state and city actions in terms of prescription drug importation were outlined in the August 2004 *NABP Newsletter* article on the topic. Several of these localities including Illinois, New Hampshire, North Dakota, and Wisconsin operate official Web sites that contain links to Canadian pharmacies. Others, like Springfield, MA, have contracted with a Canadian company to provide a particular group (such as city employees) with prescription medications via mail order. Wisconsin now offers its citizens two options: the Web site links to the Canadian pharmacies discussed earlier, or enrollment in the Illinois-originated I-SaveRx program, discussed later.

Many states including those that have started importation programs have sought waivers from FDA that would make drug importation legal. Lawmakers and politicians in these states have expressed frustration that, thus far, FDA has not granted approval for any pilot projects or waiver requests, or developed a list of criteria that would describe "safe" importation. In May 2004, the attorneys general of 18 states and one US territory sent a letter to Secretary Thompson calling for limited, legalized importation and suggesting measures to ensure drug safety.

Oregon's Pioneer Prescription Drug Project

One of the most striking aspects of Oregon's Pioneer Prescription Drug Project is the initial approach taken by the state's Governor, Ted Kulongoski: He involved the Oregon State Board of Pharmacy.

His insistence on doing so, in fact, gained the respect and the assistance of the Board, according to Gary A. Schnabel, RPh, RN, the Board's executive director. "[Kulongoski] asked the Board for direction, and at first the Board was hesitant to work on an importation scheme," says Schnabel. "But the governor was not discouraged." The governor had been watching other states and their programs, says Schnabel, but did not want to follow in their footsteps. He wanted the Board's help "to do it right." And while the Board at first was skeptical, says Schnabel, "As time went on, the governor, working with the Board, started looking at the safety factors, and the Board started to think, 'Maybe this could work.' . . . The Board said straight up that we can't endorse a program that violates federal law."

Through collaboration that involved addressing the Board's concerns for the safety and integrity of the nation's prescription drug supply came the proposed project's other unique aspect: It puts the Board in a regulatory position to perform inspections and monitor the program.

(continued on page 8)

Importation Update

(continued from page 7)

The project would accomplish this by using Oregon pharmacies to dispense the prescription drugs received from Board-registered Canadian wholesalers. Pharmacies that register with the Board to import and sell the drugs would be able to carry medications from a formulary (also selected by the Board) of 50 to 100 drugs available in Canada at a demonstrated savings, and charge dispensing fees predetermined by the Board. These imported medications would be available only for purchase using cash, removing insurance complications.

Canadian wholesalers involved in the program, already under the auspices of Health Canada, which is the Canadian equivalent to FDA, would have to pay a registration fee and meet the same standards required of US wholesalers. (Those standards may soon become more stringent than they are at present, says Schnabel. The Board has been evaluating NABP's new Model Rules for the Licensure of Wholesale Distributors, he says, and is likely to change its wholesaler licensing requirements in the not-too-distant future.) The Board would be in the position to perform inspections and monitor adherence with licensing requirements using its compliance staff.

Oregon submitted its plan to then HHS Secretary Thompson for approval on August 12, 2004, and a letter from Oregon's congressional delegation to the secretary requesting prompt approval followed on September 9. While no official response has been forthcoming as yet – and secretary Thompson's response to other states' proposals has not been positive – telephone conversations have taken place between HHS and the governor's staff, says Schnabel. With national elections over and the HHS Task Force report scheduled for impending release, however, a response may come soon. While Schnabel was impressed by the governor's interest in truly addressing safety concerns, he notes that the political atmosphere is "very hot." "We are still wondering what will happen if [HHS] says, 'No,' to the governor's request," he says. "At least everyone's still willing to sit around the table and talk."

I-SaveRx Program

At the beginning of October 2004, Illinois and Wisconsin (later joined by Missouri) launched one of the largest initiatives to date. The "I-SaveRx" program has another distinction: It is the first state-sponsored program that helps residents purchase prescription drugs not only from Canada, but also from Ireland and the United Kingdom.

In announcing the program's expansion to include Missouri, Illinois Governor Rod R. Blagojevich's 2003 proposal to launch an importation program did not receive a positive response from FDA. His response to this – in conjunction with Wisconsin Governor Jim Doyle – was to launch the I-SaveRx program. The program works through a Canadian clearinghouse, which residents of three participating states contact through a Web site or a toll-free phone number. The clearinghouse provides residents with enrollment forms as well as information on medications available through the program and prices in each of the three provider countries.

> Irish officials expressed surprise at their inclusion in the Illinois program and the three main firms that distribute drugs in Ireland also said they knew nothing of the plan.

According to Blagojevich, the program includes various safeguards to ensure patient safety. These include a requirement for new enrollees to provide a health profile form and signed prescription to the clearinghouse; a computer scan for "appropriateness" using the same drug interaction software used in Illinois pharmacies; a restriction on available medications to refills of those types used long-term and that cannot spoil during shipping; and a requirement for participating pharmacies "to agree to comply with Illinois pharmaceutical standards, and to only dispense drugs that are intended as domestic product in Canada, Ireland, or the UK," according to the governor's office.

Several organizations, however, find the safeguards to I-SaveRx suspect. Tom Engels, vice president of Public Affairs for the Pharmacy Society of Wisconsin (PSW), notes that the network of 45 international wholesalers and pharmacies are not publicly identified. In an August 19, 2004 *Chicago Tribune* article, Irish officials expressed surprise at their inclusion in the Illinois program and the three main firms that distribute drugs in Ireland also said they knew nothing of the plan. Anne Nolan, chief of the Irish Pharmaceutical Healthcare Association, told the *Tribune* that her organization would not be happy with the arrangement. "It would cause enormous problems for us to meet our local obligations here," she said.

(continued on page 9)

NABP Headquarters Moves to New Location

After more than 10 years of calling Park Ridge, IL, its Headquarters, NABP moved to 1600 Feehanville Drive, Mount Prospect, IL 60056, over the Thanksgiving holiday weekend. After a brief office closure to accommodate the move, NABP's operations resumed at the new Headquarters on November 30, 2004. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address.

The new 57,000-square-foot building will enable NABP to enhance its program and service offerings to the boards of pharmacy, candidates, and applicants and provide ample space for future growth.

For more information about NABP's new Headquarters, please see "NABP Purchases New Building for Association Headquarters" in the February 2004 *NABP Newsletter.*

If you have any questions concerning the Association's new headquarters, please contact Customer Service at custserv@nabp.net or call 847/391-4406.

Importation Update

(continued from page 8)

Wisconsin Importation Program

In addition to the I-SaveRX program, Wisconsin has its own importation site, www.drugsavings.wi.gov, which promises consumers savings of 50% or more by purchasing drugs from Canadian pharmacies. During a continuing education session at NABP's Fall Educational Conference, held November 11-14, 2004, Engels related some disturbing violations by three of the participating Canadian pharmacies that PSW found when reviewing data reports submitted over the first six months that the program was in operation.

- Prescriptions dispensed – 2,299
- PSW-identified violations – 526
- Wisconsin-identified violations – 9 (often the state did not specify a number in its reports)

PSW broke these violations into three main categories:

- Drugs sold but not listed on the Drugsavings.wi.gov Web site (346)
- Non-FDA approved drugs (174)
- Drugs sold that require refrigeration (6)

In response to PSW's criticisms, the state of Wisconsin said that the organization was the only one that "has a problem," PSW is "making up violations," the drug listing on the Web site is simply informational, and that the Web sites have ceased dispensing non-FDA approved drugs and refrigerated items. The state of Wisconsin noted that it has sent warnings to those pharmacies in violation; however, PSW still has concerns about the public health.

PSW stated its concerns in a letter sent to Wisconsin's Department of Health and Family Services, "We suspect that instead of directing patrons through the front door of their pharmacies, the Canadian pharmacies are telling their patrons to use the side door: an Internet site with even less threat of regulation.... Just one of these many violations [those discussed earlier] would be sufficient to close a licensed Wisconsin pharmacy, yet the state of Wisconsin did not end its relationship with the Canadian pharmacies."

In a July 22, 2004 letter to Wisconsin Governor Jim Doyle, FDA's Associate Commission for Policy and Planning wrote, "It is increasingly clear that the participating pharmacies continue to sell drugs to Wisconsin citizens that are in violation of the standards you have established in an attempt to assure the quality and safety of such medications and despite your Warning Letters of April 27, 2004, to these pharmacies."

In his concluding remarks, Engels stressed the importance of a federally regulated importation system that is carried out through licensed pharmacies.

Vermont Sues FDA

At about the same time that Illinois' Blagojevich announced the I-SavRx program launch and a week after FDA denied Vermont's request for a waiver of the drug importation ban, the state of Vermont filed suit against HHS and FDA. The goal: to force the government to establish rules and guidelines under which legal importation may take place.

The lawsuit claims that the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) granted waiver authority to HHS and FDA and also required them "to publish

(continued on page 23)

Deadlines Set for Advance Distribution of Proposed Resolutions

NABP will distribute proposed resolutions to allow boards of pharmacy to review the resolutions prior to NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA.

Proposed resolutions received at NABP Headquarters by April 8, 2005, to be presented and voted upon during the 101st Annual Meeting, will be distributed to the boards of pharmacy on April 22, 2005, for review prior to the meeting. This mailing will constitute **only** the pre-conference distribution of proposed resolutions. All resolutions – those distributed for early review as well as those received after April 8 – will be presented to the delegates during the Annual Meeting on Monday, May 23, by the chair of the Committee on Resolutions.

To be considered during the Annual Meeting, resolutions must adhere to the requirements of Article IV, Section 6, Part (d) of the NABP Constitution, which states:

> Any active member board, district, or committee of the Association may submit resolutions to the Association. . . . [A]ll resolutions submitted in writing to the Association at least twenty (20) days prior to the date of the Annual Meeting shall be presented at the Annual Meeting for consideration. Resolutions not presented within such time limitations may be presented during the Annual Meeting, and will be considered for adoption by the Association upon the affirmative vote of three-fourths (¾) of those Association members present and constituting a quorum.

Questions regarding resolution procedures should be directed to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters by calling 847/391-4406 or e-mailing custserv@nabp.net.

Importation Update

(continued from page 9)

guidance describing the circumstances under which [HHS and FDA] will consistently grant waivers to allow importation of prescription drugs for personal use. . . . Despite explicit direction from Congress in the MMA to promulgate regulations permitting importation of prescription drugs from Canada and guidance regarding waivers that would also allow importation," the lawsuit states, "HHS and FDA denied Vermont's petition and have taken no action to promulgate regulations or issue any guidance regarding waivers."

FDA, while stating its appreciation that Vermont is working within the US legal system to address its disagreement with federal authorities, reminded the public in an official statement that the HHS Task Force was still in progress: "Completion of this required study is critical to making an informed decision as to whether the drug importation or not program in MMA can be implemented safely."

The Vermont Board of Pharmacy, which was not involved in the waiver-seeking process, has not made a public statement regarding the matter. Its position on the reimportation of prescription drugs was published, however, in the Board's June 2003 *Vermont Board of Pharmacy Newsletter*. "The Board finds itself in a difficult, and potentially unpopular, position **to protect the public safety**," the *Newsletter* states. "The practice of importing drugs from foreign jurisdictions is illegal and has been made so to support the overriding purpose of the law, namely the protection of the **health, safety, and welfare** of the public."

NABP's Position

While NABP sympathizes with the economic concerns of those patients who face difficulties affording their prescribed medications, the Association's position is clear. "NABP does not oppose importation within the safe and secure regulatory framework of the [FDA] and state boards of pharmacy," NABP Executive Director/Secretary Carmen A. Catizone told the HHS Task Force when he testified before it in May 2004. "NABP does oppose the illegal importation of medications which is presently occurring and compromising the integrity of our medication system and state regulation of the practice of pharmacy."

Catizone also reiterated regulators' concerns about patient safety. "NABP cannot accept the premise that people must die from the illegal importation of drugs before the existing laws ensuring the safety of patients are complied with and enforced," he said. "The 'show us the bodies' strategy proposed by some legislators, governors, mayors, and other public officials is irresponsible."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

January 28, 2005

Patrick C. Lynch
Attorney General of Rhode Island
150 South Main Street
Providence, Rhode Island 02903

Dear Mr. Lynch:

I write in response to the recently enacted law authorizing the Rhode Island Department of Health to license Canadian pharmacies to import prescription medications into the state of Rhode Island. It is my understanding that regulations will soon go into effect and the Rhode Island Board of Pharmacy may soon get applications from Canadian pharmacies for licenses.

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S. approved prescription drugs have been of unknown origin and quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in Canada and to ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it was shipped back into the country in a manner that did not satisfy the refrigeration storage conditions specified in FDA-approved labeling and, therefore, that could potentially compromise the safety and effectiveness of the insulin. Because the failure to refrigerate the product may not change its appearance, American consumers may have had no way of knowing if their insulin had been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States who may import them. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of Rhode

Island were to import prescription drugs into the State of Rhode Island from Canada, it would violate the FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts conflicting state or local legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.[1]

First, virtually all drugs imported for personal use into the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus is unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 353(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with their FDA approvals in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" provision in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that all of the applicable legal requirements will be met if Canadian pharmacies ship drugs into Rhode Island. Consequently, virtually every shipment would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited...").

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C. §§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich,* 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A). In addition, those who can be found civilly and criminally liable include all who *cause* a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited").

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad. As a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into the United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Federal Preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The Supreme Court has held that,under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to preempt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of

regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984)* (quotation marks and citations omitted); *see also English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams,* 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia,* Congress has intended to occupy a field of regulation comprehensively (termed "field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). *See English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Field Preemption

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject"; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." *Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]large amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly, Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. Licensure of Canadian pharmacies by the state of Rhode Island would be inconsistent with the plain objectives of the FFDCA if such licensure authorized those Canadian pharmacies to ship into the United States drugs that violate the provisions of the FFDCA.

Implied Conflict Preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.,* 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of Rhode Island to allow imports that conflict with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

Conclusion

I hope that the preceding discussion is helpful to you. The licensure of Canadian pharmacies by the State of Rhode Island will not only result in violations of federal law, it will put citizens at risk. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality and origin. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that legalizes imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

We are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign

unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products in the U.S., and generally less expensive than the generic drugs sold elsewhere in the industrialized world. Also, the Medicare prescription drug discount card provides millions of America's seniors with discounts and coverage for their prescription medicines.

If you need additional information, please feel free to contact me.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

Footnotes

1 We will limit our discussion to drugs imported from Canada because the Rhode Island law is so limited. The legal analysis is the same for drugs imported from any foreign country.

CC: Governor of Rhode Island
Rhode Island General Assembly
Rhode Island Board of Pharmacy

AGENDA ITEM B

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: February 25, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Request from the University of California San Diego (UCSD) for Waiver of CCR, title 16, sec. 1717(e) to Install and Use An Automated Dispensing Device**

The Board of Pharmacy has received a request from UCSD for waiver of California Code of Regulations section 1717(e) to install and utilize a self-service dispensing unit at its hospital outpatient pharmacy.

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores its request for a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California. At its January meeting, the board granted a similar waiver to Safeway Inc. to install and utilize these same units at its Safeway and Vons pharmacies

The board granted the waivers of the prohibition(s) stated by that section to permit the use of an automated dispensing device that allows a patient to access his/her filled prescriptions under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

In conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients. SSPPS plans to provide the information regarding the study to the board at its April meeting.

UCSD Medical Center
HILLCREST

February 23, 2005

Patricia Harris,
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: REQUEST FOR WAIVER- CCR 1717(e)

Dear Ms. Harris:

University of California San Diego (UCSD) Medical Center, in an effort to improve patients' access to pharmacy services and therefore improve their compliance with their prescribed drug regime, respectfully requests a waiver to allow the installation and implementation of ScriptCenter, a self service prescription delivery unit manufactured by Asteres.

A waiver of 1717(e) was granted at the January board meeting for use of this machine in another California retail chain. UCSD is seeking the same waiver as we'd like to use ScriptCenter in our outpatient pharmacy locations. As you may recall, this unit is an automated, self contained unit that, at the request of a patient and through the use of a secure method designed to guard against inappropriate access, allows patients to access their refilled prescriptions for which no consultation is required.

The unit would be installed adjacent or in close proximity to the pharmacy area and may be accessed by patients during and after pharmacy hours. Prescriptions would be filled then checked by a pharmacist using the same safeguards we currently observe. The filled prescriptions would be placed into the unit under the supervision of a pharmacist. As medications are placed into the unit, security measures will be used to ensure accurate dispensing.

Other privacy and security features and additional information regarding ScriptCenter have been previously provided the Board by Asteres. However, I would be more than happy to provide further information at your request.

In conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients and would be happy to share these results with the Board as they become available.

Please place this request in the agenda of the Board's next Enforcement meeting and also in the agenda for the next full Board meeting. Please contact me at the above address or directly by phone (619) 543-3283 with any questions or comments.

Sincerely,

Charles E. Daniels, R.Ph, Ph.D.
Pharmacist-In-Chief

Department of Pharmacy *UCSD Healthcare, University of California, San Diego*
200 WEST ARBOR DRIVE, ROOM 1-317 SAN DIEGO, CALIFORNIA 92103-8765 TEL: (619) 543-6194 FAX: (619) 543-3829

AGENDA ITEM C

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

January 28, 2005

Jeffrey A. Moss
Law Offices of Jeffrey A. Moss
454 Las Gallinas Avenue #310
San Rafael, CA 94903

RE: Waiver of CCR, title 16, sec. 1717(e)

Dear Mr. Moss:

This is to acknowledge receipt of your letter dated January 24, 2005, regarding the temporary waiver that was granted to Longs Drug Stores by the Board of Pharmacy pursuant to California Code of Regulations, title 16, section 1717, subdivision (e). The waiver permits Longs Drug Stores to use an automated dispensing unit that allows a patient to pick-up his/her refill prescriptions pursuant to specified conditions.

As requested, your letter will be provided to the Board of Pharmacy at its April meeting.

Sincerely,

P. F. Harris

Patricia F. Harris
Executive Officer

LAW OFFICES OF
JEFFREY A. MOSS
454 LAS GALLINAS AVE., #310
SAN RAFAEL, CA 94903

TEL: (415) 456-2566
FAX: (415) 472-6677
e-mail: mossesq@comcast.net

January 24, 2005

VIA OVERNIGHT MAIL AND FACSIMILE: (915) 327-6308

Patricia F. Harris
Executive Officer
California State Board of Pharmacy
4000 R Street, Suite 4070
Sacramento, Ca 95814

Re: Automated Dispensing Device "Temporary Waiver"

Dear Ms. Harris:

I am the attorney for the Pharmacy Defense Fund. Mr. Fred Mayer, President of the Fund and has requested that I investigate issues related to the December 6, 2004 "Temporary Waiver" issued to Long's Drugs for the unlimited and unregulated installation of automated dispensing devices ("Devices"), and the approval of the amendment of CCR Title 16, Section 1717 to allow the devices in all California pharmacies.

The development surrounding this waiver concerns both PDF and the Board of Pharmacists Planning Services, Inc., made up of local pharmacists in both large and small pharmacies. The concerns fall into several areas. My client is concerned that the waiver itself is inadequately thought out and planned and is overly broad in scope, thereby jeopardizing the health of California patients. In addition, there is a general concern regarding the speed with which the State Board has acted and is proceeding with the Long's waiver and amendment of Section 1717, and the pending request for a similar waiver from Safeway.

I would like to first address the concern's regarding the terms of the waiver. The following areas coincide with those referred to in the wavier letter:

1. Limitation to Refills Only. The variance requires that the Devise be used for refills only. However, there are no provisions requiring Pharmacist supervision of the data entry or depositing of medicines into the Device to insure that this provision is not mistakenly violated

2. Patient's Choice. The second condition of the variance (that it be the patient's choice to use the Device) makes no mention of how the patient will know of this choice. It does not require that the patient be advised verbally or in writing, or even that there be a sign anywhere near the Device advising of this choice. The Device itself does not need any sign warning that the patient has the right not to use the machine, nor is there a requirement that the software somehow advise the patient of this right. In reality, during those hours that the pharmacy is closed, there really is no choice for the patient other than to come back at another time.

3. "Reasonable Proximity". This vague requirement gives to the store the option to put the Device as far away from the pharmacy departments as they want. It is inappropriate for patients to be going to the isle where liquor is sold or near the sandwich line or where the birthday cards are kept to obtain their medications. This type of latitude will further remove the pharmacist from the dispensing process. In addition, it removes the patient from the view of those notices and warnings that are traditionally posted at pharmacies, and further removes them from the consultation area of the pharmacy.

4. Security. The condition that the Device be secure from access by "unauthorized individuals" is also incredibly vague. I am not sure if that means that the whole device must be secured in such a way that it cannot be removed from the store premises or it means that only pharmacy personnel can have access to the interior of the Device. Does this mean that a Store Manager may access the Device to retrieve transaction information? Will a store Manager have Administrative access to the software? Or perhaps to the medicines themselves? This condition should, at the very least, require that all access to the Device be by pharmacy personnel who are authorized to handle medications.

5. Consultation Option. Is it the Board's position that a "means ...to obtain a consultation" is the retailer putting up a sign advising the patient to come back during regular pharmacy hours if they want a consult, or that they can call a number from the pay phone outside the store to speak to a pharmacist? There is no requirement that the patient even be advised that they are entitled to a consultation or how to obtain a consultation should they want one. There is no requirement that there be a phone installed in the Device or that there be one near the device. Since there is no requirement that there be a pharmacist available by phone during all hours the Device is accessible to the patient, even advising of the right to a consultation is a sham as no one will be available to consult. Once again, reality makes this condition useless: people who are there and want a consultation will not go to the trouble to obtain one. The retailer has successfully put up another barrier to consultation.

6. Need for Counseling. The variance prohibits the use of the Device if the pharmacist determines that counseling is required. While a review of the medications that have been given to the patient by that pharmacy can be reviewed on the pharmacy computer, that will not tell a pharmacist that the patient is jaundiced, or acting strangely or otherwise is suffering from side effects of a prescribed medicine from the pharmacy or a medicine from another pharmacy. A pharmacist or their assistant who sees this type of condition face to face is more likely to review medications and their effect than someone who is dropping medicine into a slot in a machine. How will the use of these Devices give the pharmacist the information needed to determine if counseling is even necessary?

Of additional concern is that the waiver appears to be a blanket waiver allowing Long's to install Devices in all of its California stores (approximately 400). This is hardly a "pilot program" as that term would be understood by anyone. When considered with the current Safeway wavier pending before the Board, it is simply an overly broad, wholesale acceptance of the Long's and Safeway business plans to reduce their costs, without any testing or evaluation at all. My clients are concerned when this attention to the needs of these retailers appears to be of more concern than the health of Californians.

The intent of the State Board in approving the Long's "temporary waiver" is made more obvious by the rapid steps taken to approve a change in the regulations and the upcoming hearing on a similar waiver applied for by Safeway. Taken together, it is clear that the Board has abandoned any pretense of a "temporary" or limited testing and evaluation of the proposed Devices. The Board does not know if or how the Devices will work in California and does not make any pretense of restricting their use to determine how they may work. Rather, it has already granted a wholesale waiver to Long's and is considering granting a waiver to Safeway, which I am told together constitute approximately fully *one quarter* of the pharmacies in California. This is certainly not a pilot program.

Effective this date I am starting my investigation into both the content and source of the background material the Board had in its possession to support that this waiver is in the interests of California patients and was a viable, safe process to institute. Since PDF does not consider the placement of these Devices into approximately 25% of the pharmacies to be either "temporary" or a form of testing, I will proceed under the assumption the Board, either as an entity are as individuals, has determined to proceed with the wholesale installation of these Devices without testing and evaluation as to their safety. Compliance with both the word and spirit of California law, and the Board's obligation to protect the citizens of this State from unsafe practices will be the measure against which we look at these matters.

PDF and PPSI strongly object to the Long's waiver as approved and to the amendment of regulations even before the Devices are tested and their safety evaluated and the expansion of this expanding this experiment to even more pharmacies through the Safeway or other waivers that may have been or will be applied for.

Please present this letter in its entirety to the Board before its upcoming meeting.

Sincerely,

LAW OFFICES OF JEFFREY A. MOSS

By: _____
JEFFREY A. MOSS, ESQ.

JAM/tim

cc: Gov. Arnold Schwarzenegger
Senator Carole Migden
Assemblyman Joe Nation
Fred Mayer, PDF
PPSI

Proposed Regulation Change to Allow the Use of a Device to Dispense Refill Prescriptions (Approved at October 2005 Board Meeting – Pending Notice of a Regulation Hearing)

Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.[1]
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d)A pharmacy may use a device to dispense refilled prescriptions provided:

(1) The patient chooses to use the device .
(2) The device is located in reasonable proximity to the licensed pharmacy premises.
(3) The device has a means to identify the patient and only release that patient's prescriptions.
(4) The device is secure from access by unauthorized individuals.
(5) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(6) The pharmacy is responsible for the prescriptions stored in the device.

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

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[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

AGENDA ITEM D

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: February 28, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Electronic Prescribing Proposed Rules**

On January 28, 2005, the Centers for Medicare and Medicaid Services (CMS) issued proposed regulations regarding electronic prescribing. The regulations propose to adopt standards for an electronic prescription drug program under Title 1 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Of interest to the state boards is the area in the regulations that addresses the federal preemption of state law. The MMA language that addresses the preemption is Section 1860D-4(e)(5).

In the proposed regulations, CMS has interpreted this section of the Act as preempting state law provisions that conflict with the federal electronic prescription program drug requirements that are adopted under part D. The deadline to submit comments to CMS on the proposed regulations is April 5, 2005.

Our counsel has advised the California law doesn't conflict with the federal electronic prescribing regulations.

The National Association of Boards of Pharmacy (NABP) is also requesting input as to whether or not the state boards will be implementing different requirements for the e-prescribing and transmission of prescriptions for controlled substances. To date, the U.S. Drug Enforcement Agency (DEA) has not released any final requirements on the electronic transmission or e-prescribing of controlled substances. NABP is asking states the following question:

> **"Do you think that the security and privacy provisions for the electronic transmission or e-prescribing of non-controlled substances and C-III to C-V controlled substances prescriptions should be equivalent and more stringent requirements in place for C-II controlled substances prescriptions only?"**

Health and Safety Code section 11164.5 specifies that a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Business and Professions Code section 4071.1, for Schedules II-V if authorized by federal law an din accordance with regulations promulgated by the Drug Enforcement Administration.

nabp

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TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY

FROM: Eleni Anagnostiadis, Patient Safety Senior Manager

DATE: February 4, 2005

RE: **CMS Releases Electronic Prescribing Proposed Rule**

On January 28, 2005, the Centers for Medicare and Medicaid Services (CMS) issued proposed regulations regarding electronic prescribing. The regulations propose to adopt standards for an electronic prescription drug program under Title 1 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Of notable interest to the state boards of pharmacy is the area addressing federal preemption of state laws. The boards are encouraged to provide comments to CMS regarding state preemption. The deadline to submit comments to CMS on the proposed regulations is **April 5, 2005.**

On behalf of the state boards of pharmacy, NABP has closely monitored the development of these electronic prescribing regulations, reviewed the proposed regulations, and has provided written and oral testimony numerous times to the National Committee of Vital Health Statistics (NCVHS) Subcommittee of Standards and Security. The MMA language addressing federal preemption of state laws follows:

Section 1860D-4(e) (5) of the Act:

> (5) Relation to State Laws. The standards promulgated under this subsection shall supercede and State law or regulation that—
>
> (A) is contrary to the standards or restricts the ability to carry out this part; and
>
> (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

In the proposed regulations, "[CMS] interpret[s] this section of the Act as preempting State law provisions that conflict with Federal electronic prescription program drug requirements that are adopted under Part D." They further go on to say that "for a State law or regulation to be preempted under this express preemption provision, the State law or regulation would have to meet the requirements of both paragraphs (A) and (B)."

Some industry representatives believe that Congress intended this preemption provision to be much broader and interpret the statute to preempt the entire field of e-prescribing.

Fortunately, this is not CMS interpretation at this point. Furthermore, some industry representatives contend that a number of States have barriers in their statutes or regulations that could impede the successful implementation of e-prescribing.

CMS is inviting public comment on their proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted. Specifically, CMS is asking for comments on whether the preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to the broader set of patient transactions and entities. Finally, CMS is seeking comment on "whether this preemption provision applies only to electronic prescription transactions or to paper transactions as well."

The proposed regulations (98 pages) are available on the CMS website at http://www.cms.hhs.gov/medicarereform/01-27master.pdf. The area addressing state preemption can be found on pages 14-18 and 87-88 of the proposed regulations.

NABP plans to submit comments and will continue to follow the development of the electronic prescribing regulations and keep you apprised of the status. NABP staff is happy to assist the state boards in drafting comments in response to the newly released electronic prescribing proposed regulations.

E-prescribing and Transmission of Controlled Substances
Another area NABP would appreciate your input is whether or not the state boards will be implementing different requirements for the e-prescribing and transmission of prescriptions for controlled substances. NABP understands that the U.S. Drug Enforcement Agency (DEA) will significantly impact the actions of the states in this area. To date, the DEA has not released any final requirements on the electronic transmission or e-prescribing of controlled substances. To help us in our discussions with the DEA and CMS, NABP would appreciate your direction to the above inquiry by responding to the following question below and return your response to csiwik@nabp.net. If you have any questions, please feel free to contact me. Thank you in advance for your assistance.

"Do you think that the security and privacy provisions for the electronic transmission or e-prescribing of non-controlled substances and C-III to C-V controlled substances prescriptions should be equivalent and more stringent requirements in place for C-II controlled substances prescriptions only?"

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

* If comments are submitted electronically, attachments should be in Microsoft Word, WordPerfect, or Excel; however, Microsoft Word is preferred.

those final standards will be required when prescription information or certain other related information is electronically transmitted among Part D sponsors (as this term is defined in the Medicare Prescription Drug Benefit final rule) and prescribing health care professionals and dispensing pharmacies and pharmacists as specified at section 1860 D-4(e)(1) of the Act for covered Part D drugs prescribed for Part D enrolled individuals.

Final standards may be adopted by the Secretary as a result of the pilot project. However, if the Secretary, after consultation with affected standard setting organizations and industry users, determines that pilot testing is not required because there is adequate industry experience with the standards, those standards may be adopted as final without pilot testing.

We refer to the final standards proposed in this rule as foundation standards because they would be the first set of final standards adopted for an electronic prescription drug program. As mentioned above and discussed further below, we believe that adequate industry experience exists with respect to the standards proposed in this rule which allows us to propose and adopt these foundation standards as final standards without pilot testing.

2. State Preemption

Nearly every State allows for the electronic transmission of prescriptions. In recent years, many States

have more actively legislated in this area. The scope and substance of this State activity, however, varies widely among the States.[1] The MMA addresses preemption of State laws at section 1860D-4(e)(5) of the Act as follows:

> (5) Relation to State Laws. The standards promulgated under this subsection shall supercede any State law or regulation that--
>
> (A) is contrary to the standards or restricts the ability to carry out this part; and
>
> (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

We propose to interpret this section of the Act as preempting State law provisions that conflict with Federal electronic prescription program drug requirements that are adopted under Part D. We view it as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards, or that restrict the ability to carry out (that is, stand as an obstacle to) the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs for Part D enrolled individuals. Consequently, for a State law or regulation to be preempted under this express preemption provision, the State law or regulation would have to meet the requirements of both paragraphs (A) and (B).

---

[1] Catizone, Carmen A. National Association of Boards of Pharmacy. Testimony before the NCVHS, July 29, 2004.

Furthermore, there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted. This interpretation closely reflects the language of the statute, and it is consistent with the presumption against Federal preemption of State law[2] and with the fundamental Federalism principles set forth in section 2 of Executive Order 13132. It is also consistent with the Department of Health and Human Service's (HHS) general position of deferring to State laws regulating the practice of pharmacy and the practice of medicine.

We understand that some industry representatives believe that the Congress intended this preemption provision to be much broader. For instance, some expressed the position that this statutory provision preempts all State laws that would in any way restrict the development of e-prescribing for all providers and payors. This position is based on the belief that the Congress intended to preempt the field of e-prescribing through this provision in the MMA. It would require an interpretation that the word "and" between paragraphs (A) and (B) is disjunctive, that is, that "and" means "or" in this context. Under this interpretation, the operative language would be "restricts the ability to carry out this part" in paragraph (A), which arguably would enable the standards and requirements adopted

[2]See *Davies Warehouse Co. v. Bowles,* 321 U.S. 144, 153, 64 S.Ct. 474, 88 L.Ed. 635 (1944), *Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644, 661, 123 S.Ct. 1855, 1867, 155 L.Ed.2d 889 (2003).

for the Federal electronic prescription drug program to preempt all State laws and regulations that restrict the Secretary's ability to carry out the goals of an electronic prescription drug program, even if they are not related to covered Part D drugs, or Part D covered individuals. They contend that some States have existing statutory or regulatory barriers that could impede the success of e-prescribing; for example, laws and regulations that were drafted with only paper prescriptions in mind, which may not be well-suited to e-prescribing applications.

This interpretation, however, does not appear to comport with the use of the word "contrary" in the statutory language which generally establishes "conflict preemption." This interpretation would seem to render paragraph (B) virtually meaningless and serve to establish "field preemption".

We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic

prescription transactions or to paper transactions as well.

3. Anti-kickback Statute Safe Harbor and Stark Exception

Section 1860D-4(e)(6) of the Act requires the Secretary to promulgate regulations that provide for a "safe harbor" under the anti-kickback statute (section 1128B(b) of the Act) and an "exception" under the physician self-referral statute (section 1877 of the Act) for certain nonmonetary remuneration related to e-prescribing information technology items and services. The statute states that--

> "The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128(b) [of the Social Security Act] and an exception to the prohibition under sub-section (a)(1) of section 1877 [of the Social Security Act] with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—
>
> (A) in the case of a hospital, by the hospital to members of its medical staff;
>
> (B) in the case of a group practice (as defined in section 1877(h)(4), by the practice to prescribing health care professionals who are members of such practice; and
>
> (C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals."

We will propose the new Stark exception for electronic prescribing in a separate rulemaking to be published in the near future. The new safe harbor under the anti-kickback

voluntarily adopted practices, and, therefore, that spending does not pertain to the thresholds of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Furthermore, we believe that the effects of adoption will be positive, rather than involve net expenditures. Regardless, even using our estimates of significant increases in the use of e-prescribing, we do not believe annual expenditures on installing this capability will reach $110 million annually. Certainly, we would expect the only entities that are required to comply, Part D sponsors (and possibly a few existing e-prescribers), to incur only minimal costs, totaling no more than a small fraction of this threshold.

With respect to States, nothing in this proposed rule mandates any expenditure by States. While some hospitals and other providers are State-owned, our conclusions with respect to each type of affected entity are not affected by ownership status.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. For the same reasons given above, we have determined that States would not incur any direct costs as a result of this proposed rule. However, as discussed previously in this preamble, and as mandated by section 1860D-4(e) of the Act, we are proposing

to preempt State law. Under the Executive Order, we are required to minimize the extent of preemption, consistent with achieving the objectives of the Federal statute, and to meet certain other conditions. We believe that, taken as a whole, this proposed rule would meet these requirements. We do seek comments from States and other entities on possible problems and on ways to minimize conflicts, consistent with achieving the objectives of the MMA, and will be undertaking outreach to States on these issues.

We have consulted with the National Association of Boards of Pharmacy directly and through participation in NCVHS hearings, and we believe that the approach we suggest as to the scope of preemption discussed earlier in the preamble provide both States and other affected entities the best possible means of addressing preemption issues. We will consult further with States before issuing the final rule. This section, together with the earlier preamble section entitled "State Preemption", constitute the Federalism summary impact statement required under the Executive Order.

I. Conclusion and Alternatives Considered

For the reasons given above, we are not preparing analyses under the RFA, section 1102(b) of the Act, or the Unfunded Mandates Reform Act. We have, nevertheless, considered the alternatives discussed below. We welcome comments on ways to lessen any unforeseen burden of our

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TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY

FROM: Eleni Anagnostiadis, Patient Safety Senior Manager

DATE: February 11, 2005

RE: **NABP Testimony – Electronic Prescribing of Controlled Substances**

On February 1, 2005, NABP testified before the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security on behalf of the state boards of pharmacy. NABP's testimony focused specifically on state issues related to the electronic transmission of controlled substances prescriptions.

During the hearing NABP informed the Committee that state board of pharmacy authority encompasses controlled and non-controlled substances. However, the regulations regarding controlled substances, including the electronic transmission and prescribing of prescriptions, bear significantly on the regulations and policies of the Drug Enforcement Administration (DEA).

To date, the DEA has not yet released their proposed regulations pertaining to the electronic transmission and prescribing of controlled substances. In all states, the regulation of the electronic transmission and prescribing of controlled substances will be impacted by any regulation or requirement issued by the DEA. NABP is hopeful that the electronic transmission and prescribing requirements for controlled and non-controlled substances will be consistent in order to minimize fragmentation and potential barriers to electronic prescribing and transmission.

Feel free to contact me at eanagnostiadis@nabp.net, 800/774-6227 or 847/391-4400 with any questions or comments regarding the electronic transmission of prescriptions.

Attachments: NABP Testimony on State Issues Related to the Electronic Prescribing of Controlled Substances
Appendix A – DEA Controlled Substance Regulations

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

Testimony on State Issues Related to the Electronic Prescribing of Controlled Substances

Submitted to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security February 1, 2005

Presented by
Eleni Z. Anagnostiadis, RPh
Patient Safety Senior Manager
National Association of Boards of Pharmacy

Mr. Chairman and Members of the Subcommittee on Standards and Security:

Thank you for the opportunity to submit the following information on state issues related to the electronic transmission of controlled substances prescriptions. The state boards of pharmacy and NABP recognize the importance of creating a regulatory environment that facilitates and regulates the electronic transmission of prescriptions for both controlled and non-controlled substances in the interest of patient safety.

NABP was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. The purpose of NABP is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

During previous testimony to the NCVHS, NABP provided comprehensive background information regarding NABP's involvement in the area of electronic transmission of prescriptions, an overview of state regulations, and information specifically addressing electronic signatures.

Pursuant to the current request of the Subcommittee, NABP's testimony focuses specifically on state issues related to the electronic transmission and prescribing of controlled substances prescriptions. It is important to note that state board of pharmacy authority encompasses controlled and non-controlled substances. However, the regulations regarding controlled substances, including the electronic transmission and prescribing of prescriptions, bear significantly on the regulations and policies of the Drug Enforcement Administration (DEA). The primary concern of NABP regarding electronic transmission and prescribing is to ensure the authenticity, legitimacy and integrity of electronically transmitted prescriptions for all prescription medications, controlled and non-controlled.

DEA Regulations for Controlled Substances

State regulations pertaining to controlled substances intersect with the federal Controlled Substances Act (CSA) and DEA authority. The CSA, which focuses on the ordering, handling, distribution and dispensing of controlled substances, is enforced by the DEA. Although states have no explicit authority to enforce federal laws, states have enacted state-specific Controlled Substances Acts which incorporate the federal CSA at a minimum and, in a limited number of states, include more stringent provisions.

The complementary and sometimes conflicting relationship of state and federal laws regarding controlled substances highlights the importance of defining federal requirements and DEA policy for the electronic transmission and prescribing of controlled substances. NABP understands that the DEA presented information to NCHVS outlining their position on the electronic transmission of controlled substances. Beyond the information presented to NCVHS, NABP is not aware of any proposed changes in the CSA or regulations from the DEA for the electronic transmission or prescribing of controlled substances.

The DEA has however authorized and participated in a pilot project at the Hines VA hospital to evaluate the effectiveness and security of transmitting controlled substances (CII – CV) prescriptions electronically. NABP is hopeful that the pilot project results will provide DEA with the information needed to develop and release requirements for the electronic transmission of controlled substances. The release of these requirements is critical to any recommendation of the NCVHS or action by the states because the states typically defer to the DEA and federal CSA for guidance. For example, Nevada's January 2005 newsletter states, "The near future will reveal a federally approved Drug Enforcement Administration electronic prescription prescribing system. The Board office has been hesitant to establish one mechanism, soon to be superceded by another. Regardless, any electronic signature transmission system needs Board of Pharmacy approval and none have been given." In any event, the more stringent laws and regulations will take precedent whether the regulation or requirement is state or federal.

NABP strongly recommends that the NCVHS exert whatever influence it may have to foster the release of regulations and requirements from the DEA. Recommendations regarding the electronic transmission and prescribing of controlled substances must encompass the actions or anticipated actions of the DEA. To do otherwise could create conflicting regulations at both the federal and state levels. As mentioned earlier, the states will follow the lead of the DEA and incorporate additional (over and above regulations for non-controlled substances) security measures and limitations placed on the electronic transmission and prescribing of controlled substances into state requirements. NABP is hopeful that the electronic transmission and prescribing requirements for controlled and non-controlled substances will be consistent in order to minimize fragmentation and potential barriers to electronic prescribing and transmission. Standards for electronic transmission and prescribing should incorporate the necessary security, accountability, and privacy domains whether the substances are controlled or non-controlled.

An analysis of current DEA regulations for controlled substances (Appendix A), appears to indicate that the DEA requirements do not directly address the electronic transmission of the prescription. It appears that the following areas of DEA regulations would be impacted by the development of federal requirements for the electronic transmission and prescribing of controlled substances:

1) DEA requirements for Schedule II controlled substances that mandate a prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner and thus do not allow for the transmission of CII prescriptions orally.
2) DEA requirements for Schedule II controlled substances that require a written prescription which must be signed by the practitioner.
3) DEA requirements for Schedule III – V controlled substances that specifically limit the transmission of prescriptions for controlled substances to oral, writing, or facsimile.

Also absent from current DEA regulations and requirements, but a significant consideration of the electronic transmission and prescribing of prescriptions, is the use of electronic or digital signatures. NABP anticipates that this area of interest will be a primary focus of any DEA regulation or requirement and developed specifically to meet the concerns of the DEA, regardless of the relation to overall standards or requirements for electronic transmission or to creating a regulatory environment that facilitates the electronic transmission or prescribing of prescriptions. As mentioned earlier, the states do not have the ability to override more stringent DEA requirements. Under current DEA regulations and requirements, prescriptions for controlled substances cannot be transmitted or prescribed electronically until the DEA updates their regulations to allow for electronic transmission and prescribing. If the standards or requirements for electronic transmission or prescribing of prescriptions do not satisfy the DEA's needs and result in a separate set of standards for electronic transmission and prescribing then a cumbersome and fragmented system will result, imposing burdens on practitioners and patients throughout the system.

State Controlled Substances Acts

In previous testimony submitted to the NCVHS, NABP noted that only five states have statutes or regulations that limit or, in some circumstances, prohibit the electronic transmission of prescriptions. In all states, the regulation of the electronic transmission and prescribing of controlled substances will be impacted by any regulation or requirement issued by the DEA. Absent any federal regulations or requirements, the states will be forced to develop requirements for the electronic transmission and prescribing of controlled substances. In the past, the states have treated controlled substances differently than non-controlled substances and imposed additional requirements for controlled substances because of the highly addictive and susceptibility to diversion that characterize controlled substances.

Upon conducting a brief search of state regulations regarding the electronic transmission of controlled substances, NABP identified New Jersey and Wisconsin as states that have language in their regulations that would potentially allow for the electronic transmission of controlled substances prescriptions pursuant to the DEA establishing federal regulations that would allow for the electronic transmission of controlled substances. Wisconsin regulations do not specifically include language pertaining to the electronic transmission of CIII –V prescriptions but clearly do not allow for the electronic transmission of CII prescriptions. As an example of a state regulation addressing electronic transmission of controlled substances, New Jersey's language reads:

NJ BReg 13:39-5.8B. Electronically Transmitted Prescriptions. (Adopted Sept. 15, 2003. Updated 6/2004.)

(a) A pharmacist may accept for dispensing an electronic prescription, consistent with the requirements of this section. For purposes of this section, electronic prescription means a prescription which is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

A pharmacist may fill a prescription for a Schedule II controlled substance transmitted electronically, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. **If permitted by federal law, and in accordance with federal requirements, an electronic prescription shall serve as the original signed prescription.**

(i) A pharmacist may fill a prescription for a Schedule III, IV, or V controlled substance transmitted electronically, provided that the pharmacist has obtained original signed prescription, an oral prescription, or a facsimile prescription from the prescribing practitioner or the prescribing practitioner's authorized agent prior to the dispensing. **If permitted by federal law, and in accordance with federal requirements, and electronic prescription shall serve as the original signed prescription.**

According to the NABP *2005 Survey of Pharmacy Law*, all fifty states as well as the District of Columbia have a state-specific Controlled Substance Act (CSA). While the CSA in nearly half the states falls under the purview of the Board of Pharmacy, in the remaining states, some aspects of the regulation of controlled substances may fall to another state agency such as the Dangerous Drugs Bureau, Drugs and Narcotics Agency, or Bureau of Drug Control. It is through state-specific CSA's that state regulatory agencies define their authority for the regulation of controlled substances. Ultimately, authority for the electronic transmission and prescribing of prescriptions for controlled substances will rest with the individual state board of pharmacy, or similarly charged agency, because this practice is an integral component of the practice of pharmacy. In states where other agencies share the regulatory authority for controlled substances, again the board of pharmacy or similarly charged-agency will bear responsibility for the electronic transmission and prescribing of prescriptions, controlled and non-controlled, and regulate other requirements through a complementary arrangement.

Recommendations from the NCVHS must account for the regulations and requirements of the DEA as well as existing state regulations or requirements. NABP again urges caution in any preemption of state laws and regulations, particularly those governing the dispensing of controlled substances because of the highly addictive nature of these substances and problems with diversion and trafficking the states have experienced.

Conclusion

In closing, NABP recognizes the benefits of the electronic transmission of prescriptions and understands the positive impact this technology can have on patient safety and the prescribing of prescription orders. Electronic or digital signature considerations and qualifications will be critical to the entire validation process and extremely dependent on the technology and standards used to ensure the authenticity, legitimacy and integrity of the electronically transmitted prescription. While many arguments can be made to support the rapid adoption of electronic prescribing, consideration should be given to the development of a national standard that is focused on patient safety, public protection, and the provision of quality health care.

NABP is committed to assisting the NCVHS, CMS, and other interested stakeholders in developing standards, laws, and regulations for electronic transmission which ensure appropriate regulation and safeguards that enhance public safety and engender public trust.

Thank you once again, for the opportunity to address this important issue.

Drug Enforcement Agency (DEA) Controlled Substances Regulations
Comparison to State Regulations
Impacted by Electronic Prescribing

Appendix A

DEA Regulations for Controlled Substances	*Do State Regulations Differ from DEA Regulations?*	*Impacted by Electronic Transmission? Different from Paper Requirements?*
Prescription Records (Storage – not transmission)		
Controlled substance prescriptions must be filed in one of three ways: CII, CIII-V, Non controlled		No
Must be readily retrievable for DEA inspection		No
Maintain prescriptions for 2 years	Yes, states require prescriptions to be kept anywhere from 2 – 7 years, depending on the state	No
Prescription Requirements		
Prescription must be dated and signed on the date when issued		No
Prescription must include: o Patient's full name and address o Prescribers name, address, and registration (DEA) number o Drug name, strength, dosage form, quantity prescribed, directions for use, and number of refills		No
Where an oral prescription is not permitted (CII), a prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner.	No - defer to DEA	**Yes**
Practitioner is responsible for making sure the prescription conforms in all essential respects to the law and regulations.		No
An individual (i.e. secretary or nurse) may be designated by the practitioner to prepare prescriptions for his/her signature.		No

Prepared by the National Association of Boards of Pharmacy
January 2005

Drug Enforcement Agency (DEA) Controlled Substances Regulations
Comparison to State Regulations
Impacted by Electronic Prescribing

Appendix A

DEA Regulations for Controlled Substances	*Do State Regulations Differ from DEA Regulations?*	*Impacted by Electronic Transmission? Different from Paper Requirements?*
Schedule II Substances		
Requires written prescription which must be signed by practitioner	No – defer to DEA	**Yes**
No time limit when a schedule II must be filled after being signed by prescriber		No
No quantity limits on any prescriptions		No
Oral order only permitted in an emergency situation Called in – follow up Rx within 7 days		No
No refills allowed		No
Schedule III - V Substances		
May be communicated orally, in writing, or faxed	No – defer to DEA	**Yes**
May be refilled if authorized on the prescription o III – IV – refilled up to five times within 6 months of date of issue o Documenting refills		No

Prepared by the National Association of Boards of Pharmacy
January 2005

National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY

FROM: Eleni Anagnostiadis, Patient Safety Senior Manager

DATE: December 17, 2004

RE: NABP Testimony on Electronic Signatures

On December 8, 2004, NABP testified before the National Committee of Vital Health Statistics (NCVHS) Subcommittee on Standards and Security on behalf of the state boards of pharmacy. The charge of NCVHS is to provide the Centers for Medicare and Medicaid Services (CMS) and Secretary Tommy Thompson with recommendations regarding national electronic prescribing standards as outlined in the Medicare Modernization Act (MMA) of 2003.

NABP previously testified before this same Committee in July 2004 during which a comprehensive background was given regarding NABP's involvement over the past twenty years in the area of electronic transmission of prescriptions. The December 8th testimony focused specifically on electronic signatures.

During the hearing NABP informed the Committee that our primary concern regarding electronic prescribing is to ensure the authenticity, legitimacy and integrity of electronically transmitted prescriptions. NABP's position states that either electronic or digital signatures can be used to process electronic prescriptions as long as the technology used allows for a secure transmission. NABP also suggested that NCVHS consult with the Drug Enforcement Agency (DEA) regarding their position on signatures required for the electronic transmission of controlled substances.

NABP will continue to work with NCVHS in defining the electronic transmission of prescriptions, developing a national electronic prescribing standard, and creating an environment that fosters the safe and appropriate utilization of this technology.

Feel free to contact me at eanagnostiadis@nabp.net or 847.391.4400 with any questions or comments regarding the electronic transmission of prescriptions.

Attachments: NABP Testimony on Electronic Signatures

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

Testimony on Electronic Signatures
Submitted to the National Committee on Vital and Health Statistics
Subcommittee on Standards and Security
December 8, 2004

Presented by
Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary
And
Eleni Z. Anagnostiadis, RPh
Patient Safety Senior Manager
National Association of Boards of Pharmacy

Mr. Chairman and Members of the Subcommittee on Standards and Security: thank you for the opportunity to submit the following information on the important and developing concept of electronic signatures as they relate to the electronic transmission of prescriptions. The state boards of pharmacy and NABP recognize the importance of regulating the electronic transmission of prescriptions within a regulatory framework that focuses on patient safety.

NABP was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. The purpose of NABP is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

During our previous testimony, presented on July 28, 2004, NABP provided the NCVHS with comprehensive background information regarding NABP's involvement over the past twenty years in the area of electronic transmission of prescriptions. In November 2001, an NABP task force was convened to study the electronic transmission of prescriptions. The task force noted that approximately 44 states allowed for the electronic transmission of prescriptions, in some form, either through explicit statutory and regulatory language defining and allowing its use or by default in omitting any prohibition of this activity. In 2004, that number is closer to 50.

Our testimony today will focus specifically on electronic signatures. NABP's primary concern regarding electronic prescribing is to ensure the authenticity, legitimacy and integrity of electronically transmitted prescriptions. *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* suggests that either an electronic or a digital signature can be used to process electronic prescriptions as long as the technology that exists allows for a secure transmission.

Electronic Signature Defined in the NABP *Model Act*
NABP recognizes the importance of ensuring the integrity and authentication of prescriptions transmitted through electronic channels. Based on a NABP task force recommendation in September 2001, NABP incorporated the Food and Drug Administration's (FDA) definitions of "electronic signature" and "digital signature" into model regulations for electronic transmission of prescriptions.

The Model Act defines the concepts of electronic and digital signature as follows:

"**Electronic signature**" is an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

"**Digital signature**" means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

The NABP *Model Act,* language regarding electronic and digital signatures is as follows:

> "If an **electronically transmitted** Prescription Drug Order, prescribing Practitioner's **electronic or digital signature**;"

Nearly half of the states require some form of electronic signature and/or other secure method of validation, while a few states require digital signatures for electronically transmitted prescriptions (Attachment A). One state had required use of digital signatures but updated their regulations to allow for use of electronic signatures. Roughly one-third of the states do not specifically address this issue.

Many state regulations also include that the electronic order must identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission. The language found in a number of state practice acts and regulations can also be traced back to the NABP *Model Act.*

Ensuring the Integrity of the Prescription Order
NABP's experience with the electronic transmission of prescriptions and electronic signature extends beyond the definitions and provisions of the NABP Model Act. The Verified Internet Pharmacy Practice Sites (VIPPS) program, which was launched in 1999, identifies and verifies legal and legitimately operating Internet pharmacies. The electronic transmission of prescriptions by Internet pharmacies is an area specifically identified in the VIPPS Criteria (Attachment B) and examined during the accreditation inspection. Again, NABP's particular interests concern the authentication of the prescription and maintaining the integrity of the prescription process.

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:

> ***Prescription Information***
> *Maintain and enforce policies and procedures that assure the integrity, legitimacy, and authenticity of the Prescription Drug Order and seek to prevent Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies. Maintain and enforce policies and procedures that assure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without there being a pre-existing patient-prescriber relationship that has included an in-person physical examination.*

NABP is also concerned that the transmission of prescriptions electronically must safeguard patient confidentiality and be conducive to patient counseling and drug use review. The NABP Model Act and VIPPS criteria include several references to this concern. Specifically, from the VIPPS Criteria:

> ***Patient Information***
> *Maintain and enforce policies and procedures ensuring reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver, in accordance with applicable state law;*
>
> *Obtain and maintain in a readily accessible format, patient medication profiles and other related data in a manner that facilitates consultation with the prescriber, when applicable, and counseling of the patient or caregiver;*
>
> *Conduct a prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law; and*
>
> *Maintain and enforce policies and procedures to assure patient confidentiality and the protection of patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution while such information is being transmitted via the Internet and while the pharmacy possesses such information.*

DEA Regulations for Controlled Substances

It is important to note that although state regulations regarding electronic and digital signatures include controlled substances prescriptions, the basis for, or overriding authority on the permissiveness of the electronic transmission of controlled substances prescriptions will be the Drug Enforcement Agency (DEA). States are working cooperatively with the DEA to achieve a productive intertwining of federal and state requirements for the transmission of controlled and non-controlled prescription orders. To date, the DEA has not yet released their regulations pertaining to electronic/digital signatures for controlled substances prescriptions that are transmitted electronically. The NCVHS, as it is well aware, should take the DEA regulations, once released, into consideration prior to providing a recommendation on electronic signatures to the

Secretary of Health and Human Services (HHS). The electronic signature requirements for controlled and non-controlled substances should be consistent in order to minimize fragmentation and potential barriers to electronic prescribing.

Conclusion

In closing, NABP recognizes the benefits of the electronic transmission of prescriptions and understands the positive impact this technology has on patient safety and the facilitation of the processing of prescription orders. Electronic or digital signature considerations and qualifications will be critical to the entire validation process and extremely dependent on the technology and standards used to ensure the authenticity, legitimacy and integrity of the electronically transmitted prescription. While many arguments can be made to support the rapid adoption of electronic prescribing, consideration should be given to the development of a national standard that is focused on patient safety, public protection, and the provision of quality health care.

NABP is committed to assisting the NCVHS, CMS, and other interested stakeholders in developing standards, laws, and regulations for electronic transmission which ensure appropriate regulation and safeguards that enhance public safety and engender public trust.

Thank you once again, for the opportunity to address this important issue.

ATTACHMENT A

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Alabama	Yes		
Alaska	Yes		
Arizona	Yes		
Arkansas	Yes		
California	Yes		The "furnisher" shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent
Colorado	Yes		
Connecticut	Yes		
Delaware	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of the order
District of Columbia	Not addressed	Not addressed	Not addressed
Florida	Yes		Pharmacist shall take such measures necessary to ensure the validity of all prescriptions received
Georgia	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of the order
Hawaii	Yes Under jurisdiction of the Department of Health, Food, and Drug Branch	Prescriptions must be irrefutably traceable to prescriber by image of signature and or oral designation, electronic signature or digital signature.	Practitioners and pharmacist to exercise prudent and professional judgment

December 2004

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Idaho	Yes. The code section addressing this issue is not part of pharmacy code or rules.		
Illinois	Yes, no specific regulation. Act allows for electronic prescriptions.		
Indiana	Not prohibited		
Iowa	Yes	Computer transmission must include prescriber's electronic signature (a confidential personalized digital key, code, or number used for secure electronic data transmissions which identifies and authenticates the signatory) and is deemed the original is all other requirements are met	
Kansas	Yes		Order must identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission; responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of rx order
Kentucky	Yes		
Louisiana	Yes		Verification of accuracy and authenticity is responsibility of pharmacist
Maine	Yes	If the order is transmitted by email or file transfer, it must contain the signature or electronic equivalent of a signature of the prescriber and shall be electronically encrypted (to prevent access, alteration or use by unauthorized person)	Order must be verified and authenticated by the pharmacist; must identify the transmitter's telephone number for verbal confirmation, the time and date of transmission, and the identity of the drug outlet intended to receive the transmission

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Maryland	Yes	Board of Pharmacy regulations allow for prescriber signatures to be sent electronically is they possess ONE of the four elements listed in COMAR 10.34.20 Format of Prescription Transmission: 1)Signature of prescriber; 2) An alternative method of communication acceptable for commerce which indicates the prescriber personally originated or approved the prescription; 3) Audio or visual interaction with the prescriber or agent; 4) The prescription being processed by a commercial intermediary, which guarantees security of transmission.	Pharmacist responsible for ensuring validity of rx order; order must be conveyed in a form containing an alternative method of communication for indicating that an authorized prescriber has personally originated or approved the prescription or be processed by a commercial intermediary that guarantees the confidentiality and security of the transmission process in a manner approved by the board
Massachusetts	Yes	Must have an electronic signature (defined as "an electronic sound, symbol or process attached to or logically associated with an rx record and executed or adopted by a practitioner with the intent to sign and prescription record") which is unique to an identified practitioner, originated solely by and under the ultimate control of the practitioner, and capable of verification;	Electronically transmitted orders must be validated and authenticated (meaning the identities of the parties sending & receiving electronic rx data are duly verified); must utilize a system that includes a combination of technical security measures
Michigan	Yes	Prescription order to include name and address of the prescriber, an electronic signature or other board-approved means of ensuring prescription validity, prescriber's telephone number for verbal confirmation of the order., the date and time of transmission, and the name of the pharmacy intended to receive the transmission;	Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order; technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement
Minnesota	Yes		

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Mississippi	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order;
Missouri	Yes	Electronic signatures (a confidential personalized digital key, code, number or other identifier used for secure electronic data transmissions which identifies and authenticates the signatory) may be sent as part of an electronic transmission prescription to a pharmacy or it may be applied to a hard copy to be provided to the patient	Pharmacist shall ensure the validity of the prescription as to its source of origin
Montana	Yes	Both prescriber and pharmacist must have secure (encrypted or encoded) system for electronic transmission from computer to computer; prescriber's electronic signature or other secure method of validation shall be provided with electronically transmitted order	Pharmacist is responsible for assuring the validity of the electronically transmitted prescription
Nebraska	Yes	Prescription must be a written, signed medical order and stature defines signature as a handwritten or **digital signature.** Cannot dispense based on electronic signature.	

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Nevada	Yes	Electronically transmitted prescriptions are not required to contain the signature of the prescriber if it contains a facsimile signature, security code or other mark that uniquely identifies the practitioner or a voice recognition system, biometric identification technique or other security system approved by the board is used to identify the practitioner Electronic prescription computer systems must be approved by BoP, and system must require user provide unique identification (fingerprint / retinal scan, PIN, or other) before each use	
New Hampshire	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order
New Jersey	Yes	A practitioners electronic signature or other secure method of validation shall be provided with the electronic prescription unless the rx is transmitted by an authorized agent	Prescriber must provide DEA number or prescriber's license number at time of transmittal; verifying authenticity of questionable orders is ultimate responsibility of pharmacist, who may request verbal verification from prescriber or agent if rx is in question
New Mexico	Yes	Prescriber's electronic signature, or other secure method of validation shall be provided with the electronically transmitted prescription or drug order	Pharmacist must exercise "professional judgment' regarding the accuracy and authenticity of the prescription
New York	Yes	Prescription must contain prescriber's signature (or electronic equivalent) and be electronically encrypted	

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
North Carolina	Yes	Electronically transmitted prescriptions shall be transmitted by an authorized practitioner or his designated agent and contain either a written signature or an electronic signature unique to the practitioner; order shall include transmitter's phone number for verbal confirmation, time and date of transmission, and identity of the pharmacy intended to receive the transmission;	Pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of order
North Dakota	Yes		
Ohio	Yes	Each electronic transmission system must have "true positive identification" of the prescriber sending the prescription; pharmacist must be able to verify that the rx is legitimate; computer generated signatures are not recognized as a means of positive ID	Prescription not valid unless Board-approved system assures that only authorized prescribers have issued the electronically transmitted prescription
Oklahoma	Yes		
Oregon	Yes		
Pennsylvania	Yes		
Rhode Island	Yes	Prescription must contain the prescriber's electronic or digital signature (defined as an electronic sound, symbol or process attached to or associated with the rx)	
South Carolina	No		
South Dakota	No		

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Tennessee	Yes	Order must include phone number or authorized prescriber (to allow verbal confirmation of the validity and accuracy of order), date & time of transmission, name of pharmacy to which order is being transmitted, prescribing practitioner's electronic signature or other secure method of validation (electronic signature is process that secures the user authentication, or proof of identity at the time signature is generated– ex. biometrics, fingerprints, retinal scans, hand written signature verification, etc.), and identity of prescriber's agent if applicable.	
Texas	Yes		Pharmacist to exercise sound professional judgment with respect to the accuracy and authenticity of rx order
Utah	Yes		Order to contain the date and time of transmission and name of the pharmacy intended to receive the transmission; pharmacist's responsibility to exercise professional judgment regarding the accuracy and authenticity or order
Vermont	Yes		R.Ph. exercise professional judgment re accuracy, validity, and authenticity of order
Virginia	Yes		
Washington	Yes		
West Virginia	Yes		Order must show date and time of transmission and name of person transmitting the order

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ELECTRONIC SIGNATURE REQUIREMENTS
(ATTACHMENT A) STATE COMPARISON

State	Allow for Electronic Transmission of Prescriptions	Electronic or Digital Signature Required for Non-Controlled Substance Prescriptions	Prescription Authentication for Non-Controlled Substance Prescriptions
Wisconsin	Yes	Order must include electronic signature, or other secure method of validation, sender's name and phone number for oral confirmation, time and date of transmission, pharmacy intended to receive the transmission, and is designated as "electronically transmitted prescription" or something to that effect;	
Wyoming	Yes	Electronically transmitted prescriptions must be authenticated by a **digital signature**/electronic signature (depending on method of transmission)	Responsibility of pharmacy to exercise professional judgment regarding the accuracy, validity, and authenticity of the order

The purpose of this chart is to highlight the electronic signature language that exists in the various state regulations. This chart is by no means all-inclusive or comprehensive. Controlled substances are not addressed.

ATTACHMENT B

Verified Internet Pharmacy Practice Sites (VIPPS)®
Criteria

Licensure and Policy Maintenance

Qualifying VIPPS Pharmacies (see definitions) must:

1) Provide NABP with the information necessary to verify that the VIPPS pharmacy is licensed or registered in good standing to operate a pharmacy and/or engage in the practice of pharmacy with all applicable jurisdictions;

2) Provide NABP with the information necessary to verify that all persons affiliated with the site, including those affiliated through contractual or other responsible arrangements, that are engaging in the practice of pharmacy are appropriately licensed or registered and in good standing in all applicable jurisdictions;

3) Maintain and enforce a comprehensive policy and procedure that documents how the pharmacy's policies and procedures are organized, authorized for implementation, revised, retired and archived; and

4) Comply with all applicable statutes and regulations governing the practice of pharmacy where licensed or registered, and comply with the more stringent law or regulation as determined by conflicts of law rules. VIPPS pharmacies must maintain and enforce policies and procedures that address conflicts of law issues that may arise between individual states or between state and federal laws and regulations. Said policies and procedures must assure compliance with applicable laws including generic substitution laws and regulations, and must prohibit unauthorized therapeutic substitution from occurring without necessary patient or prescriber authorization and outside of the conditions for participation in state or federal programs such as Medicaid.

Prescriptions

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:

5) Maintain and enforce policies and procedures that assure the integrity, legitimacy, and authenticity of the Prescription Drug Order and seek to prevent Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies. Maintain and enforce policies and procedures that assure that prescription medications are not prescribed or dispensed based upon telephonic, electronic, or online medical consultations without there being a pre-existing patient-prescriber relationship that has included an in-person physical examination.

Patient Information

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, must:

6) Maintain and enforce policies and procedures ensuring reasonable verification of the identity of the patient, prescriber, and, if appropriate, caregiver, in accordance with applicable state law;

7) Obtain and maintain in a readily accessible format, patient medication profiles and other related data in a manner that facilitates consultation with the prescriber, when applicable, and counseling of the patient or caregiver;

8) Conduct a prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law; and

9) Maintain and enforce policies and procedures to assure patient confidentiality and the protection of patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution while such information is being transmitted via the Internet and while the pharmacy possesses such information. [The NABP Guidelines for the Confidentiality of Patient Health Care Information as It Relates to Patient Compliance and Patient Intervention Programs can serve as a useful resource for addressing the confidentiality and security of patient data.]

Communication

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria must:

10) Maintain and enforce policies and procedures requiring pharmacists to offer interactive, meaningful consultation to the patient or caregiver;

11) Maintain and enforce policies and procedures establishing a mechanism for patients to report, and the VIPPS Pharmacy to take appropriate action regarding, suspected adverse drug reactions and errors;

12) Maintain and enforce policies and procedures that provide a mechanism to contact the patient and, if necessary, the prescriber, if an undue delay is encountered in delivering the prescribed drug or device. Undue delay is defined as an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan;

13) Maintain and enforce policies and procedures establishing mechanisms to inform patients or caregivers about drug recalls; and

14) Maintain and enforce policies and procedures establishing mechanisms to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications.

Storage and Shipment

Qualifying VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria, must:

15) Ship controlled substances to patients via a secure and traceable means; and

16) Assure that medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopeia (USP), during storage and shipment.

ATTACHMENT B

Over-the-Counter Products

Qualifying VIPPS Pharmacies must:

17) Comply with all applicable federal and state laws regarding the sale of Over-the-Counter Products identified as precursors to the manufacture or compounding of illegal drugs.

Quality Improvement Programs

Qualifying VIPPS Pharmacies must:

18) Maintain a Quality Assurance/Quality Improvement Program.

Reporting to NABP

Qualifying VIPPS Pharmacies must:

19) Notify NABP within thirty (30) days of any change of information provided as part of the verification process, including change in pharmacist-in-charge, or involving data displayed on the VIPPS Web site. VIPPS pharmacies shall notify NABP in writing within ten (10) days of ceasing operations. The written notification shall include the date the pharmacy will be closed, and an affirmation that all VIPPS Seals and references to the VIPPS program have been removed from the Web site and wherever else they are displayed.

AGENDA ITEM E

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: February 28, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Prescribing Authority for Naturopathic Doctors**

The attached article appeared in the board's January 2005 newsletter regarding the authority of Naturopathic Doctors to prescribe. Since this article appeared, the board has been working with the Bureau of Naturopathic Medicine to further clarify this authority. The board has requested a legal opinion from Staff Counsel Dana Winterrowd on this issue for distribution at the Enforcement Committee meeting.

Necessity for Pharmacist to Check Automation/Robotic Dispensing

The Board of Pharmacy recently reviewed a request from McKesson Automation, Inc. (McKesson) to approve a proposed protocol for use in hospital and institutional pharmacies that would not require licensed pharmacists to check every medication dispensed by its automated dispensing system, ROBOT-Rx. McKesson proposed a protocol whereby a pharmacist would check 100 percent of the medications packaged by the ROBOT-Rx on a daily basis for at least 30 days after the ROBOT-RX is deployed. After the 30 days, the pharmacist would then taper off to sampling only 5-10 percent of the doses dispensed.

Pharmacy Law is silent on the question about how a pharmacist must check medication dispensed from automated delivery systems, aside from those provisions relating to placement of such a system in nonprofit or free clinics (Business & Professions Code [B&PC] section 4186). There is no statute or regulation specifically requiring that a pharmacist check every dose dispensed by an automated drug delivery system located in an inpatient setting, nor is there any statute or regulation absolving the dispensing pharmacist of this responsibility. Because of this silence, McKesson concluded that it is within the Board's discretion to approve a protocol that would apply specifically to ROBOT-Rx technology.

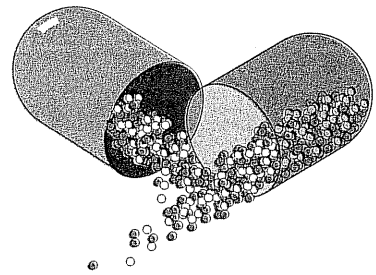
In denying McKesson's request, the Board considered the opinions of its counsel, which follow, in relevant part:

The Board has no relevant statutory authority to approve a protocol, and to do so may constitute an impermissible underground regulation. Under current law, it is the responsibility of individual licensees to determine the level of error risk they are willing to assume, and the steps they take to reduce or eliminate that risk.

Pharmacy Law is violated where a prescription is dispensed in an insufficiently or inaccurately labeled container (B&PC sections 4076-4078), where the drug dispensed deviates from requirements of a prescription (Title 16, California Code of Regulations [CCR] section 1716), or where the prescription is dispensed containing significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations (CCR section 1761). These provisions apply to all dispensing, regardless of the setting.

Any licensee that chooses to implement a reduced-error-checking protocol like that suggested by McKesson is assuming the risk of any errors that result. Even if such errors are less likely with the ROBOT-Rx system, the licensee is responsible for any errors that do occur. It may therefore be a risk for licensees to implement a protocol that increases the chance of such an error, however minor, by eliminating 100 percent of the human double-checking that could perhaps catch and correct those few errors made by the machine(s). Any licensee implementing such a protocol will be subject to discipline for any errors that do occur (as would any licensee responsible for errors from any other delivery system). It is possible the severity of the violation may even be greater where the error could have been caught had not such a sampling protocol been in place.

In the absence of any statutes or regulations exempting a dispensing pharmacist or pharmacy working with an automated drug delivery system from the general requirements pertaining to prescription accuracy and propriety of drug delivery, it is the responsibility of the dispensing pharmacist and pharmacy to ensure 100 percent accuracy of the dispensing. Licensees electing to save costs by reducing their level of error checking do so at their own risk and that of the patient.



Naturopathic Doctors Added to Prescriber List

Section 3640.5 of the Business & Professions Code authorizes naturopathic doctors (NDs) to furnish or order Schedule III-V drugs, and emergency regulations authorizing NDs to prescribe have recently been approved.

Licensing of NDs by the Bureau of Naturopathic Medicine has begun and will be limited to those who have completed educational and other licensing requirements. Licensed NDs will function in accordance with standardized procedures or protocols developed with his or her supervising physician and surgeon.

Prescriptions written by NDs must contain:

- The printed or stamped name, license number and **furnishing number** of the ND,
- The ND's federal controlled substances registration number, if the prescription is for a controlled substance. This requirement may be met by stamping the ND's federal registration number on the prescription.
- The signature of the ND.

Updated information regarding this issue will be published in this newsletter when it becomes available.

Senate Bill No. 907

CHAPTER 485

An act to amend Sections 101, 144, 146, and 149 of, and to add and repeal Chapter 8.2 (commencing with Section 3610) of Division 2 of, the Business and Professions Code, and to amend Section 13401.5 of the Corporations Code, relating to professions and vocations, and making an appropriation therefor.

[Approved by Governor September 22, 2003. Filed with Secretary of State September 22, 2003.]

LEGISLATIVE COUNSEL'S DIGEST

SB 907, Burton. Professions and vocations: naturopathic doctors.

(1) Existing law establishes boards and bureaus within the Department of Consumer Affairs that are responsible for licensing and regulating persons practicing various healing arts disciplines.

This bill would establish, until July 1, 2009, the Naturopathic Doctors Act, to be administered by the Bureau of Naturopathic Medicine created within the Department of Consumer Affairs. The bill would specify various standards for the licensure and regulation of naturopathic medicine that the bureau would enforce. The bill would create the Naturopathic Doctor's Fund, and would require fees collected by the bureau to be deposited into the fund. The bill would specify that the moneys in the fund are available to the bureau only upon appropriation by the Legislature, but it would appropriate all money other than specified revenue received and credited to the fund in the 2003–04 fiscal year to the bureau to implement the act's provisions. The bill would make the provisions of the act relating to the fund operative on January 1, 2004, but would make the remainder of the act operative on July 1, 2004. The bill would require the department to certify that sufficient funds are available in the Naturopathic Doctor's Fund prior to implementation. The bill would make additional related changes.

(2) Existing law requires specified regulatory boards within the department to obtain fingerprints from a licensing applicant to conduct a criminal history check.

This bill would extend this requirement to the Bureau of Naturopathic Medicine, the Contractors' State License Board, and the Structural Pest Control Board.

(3) Because the bill would make the violation of certain of its provisions a crime, it would impose a state-mandated local program.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

(5) This bill would incorporate additional changes in Section 13401.5 of the Corporations Code proposed by AB 123 that would become operative only if AB 123 and this bill are both enacted and become effective on or before January 1, 2004, and this bill is enacted last.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 101 of the Business and Professions Code is amended to read:

101. The department is comprised of:

(a) The Dental Board of California.

(b) The Medical Board of California.

(c) The State Board of Optometry.

(d) The California State Board of Pharmacy.

(e) The Veterinary Medical Board.

(f) The California Board of Accountancy.

(g) The California Architects Board.

(h) The Bureau of Barbering and Cosmetology.

(i) The Board for Professional Engineers and Land Surveyors.

(j) The Contractors' State License Board.

(k) The Bureau for Private Postsecondary and Vocational Education.

(*l*) The Structural Pest Control Board.

(m) The Bureau of Home Furnishings and Thermal Insulation.

(n) The Board of Registered Nursing.

(o) The Board of Behavioral Sciences.

(p) The State Athletic Commission.

(q) The Cemetery and Funeral Bureau.

(r) The State Board of Guide Dogs for the Blind.

(s) The Bureau of Security and Investigative Services.

(t) The Court Reporters Board of California.

(u) The Board of Vocational Nursing and Psychiatric Technicians.

(v) The Landscape Architects Technical Committee.

(w) The Bureau of Electronic and Appliance Repair.

(x) The Division of Investigation.

(y) The Bureau of Automotive Repair.

(z) The State Board of Registration for Geologists and Geophysicists.

(aa) The Respiratory Care Board of California.
(ab) The Acupuncture Board.
(ac) The Board of Psychology.
(ad) The California Board of Podiatric Medicine.
(ae) The Physical Therapy Board of California.
(af) The Arbitration Review Program.
(ag) The Committee on Dental Auxiliaries.
(ah) The Hearing Aid Dispensers Bureau.
(ai) The Physician Assistant Committee.
(aj) The Speech-Language Pathology and Audiology Board.
(ak) The California Board of Occupational Therapy.
(a*l*) The Osteopathic Medical Board of California.
(am) The Bureau of Naturopathic Medicine.
(an) Any other boards, offices, or officers subject to its jurisdiction by law.

SEC. 2. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) shall require an applicant to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks. Any agency designated in subdivision (b) may obtain and receive, at its discretion, criminal history information from the Department of Justice and the United States Federal Bureau of Investigation.

(b) Subdivision (a) applies to the following boards, bureaus, or committees:
(1) California Board of Accountancy.
(2) State Athletic Commission.
(3) Board of Behavioral Sciences.
(4) Court Reporters Board of California.
(5) State Board of Guide Dogs for the Blind.
(6) California State Board of Pharmacy.
(7) Board of Registered Nursing.
(8) Veterinary Medical Board.
(9) Registered Veterinary Technician Committee.
(10) Board of Vocational Nursing and Psychiatric Technicians.
(11) Respiratory Care Board of California.
(12) Hearing Aid Dispensers Advisory Commission.
(13) Physical Therapy Board of California.
(14) Physician Assistant Committee of the Medical Board of California.
(15) Speech-Language Pathology and Audiology Board.
(16) Medical Board of California.

(17) State Board of Optometry.
(18) Acupuncture Board.
(19) Cemetery and Funeral Bureau.
(20) Bureau of Security and Investigative Services.
(21) Division of Investigation.
(22) Board of Psychology.
(23) The California Board of Occupational Therapy.
(24) Structural Pest Control Board.
(25) Contractors' State License Board.
(26) The Bureau of Naturopathic Medicine.

SEC. 3. Section 146 of the Business and Professions Code is amended to read:

146. (a) Notwithstanding any other provision of law, a violation of any code section listed in subdivision (c) or (d) is an infraction subject to the procedures described in Sections 19.6 and 19.7 of the Penal Code when:

(1) A complaint or a written notice to appear in court pursuant to Chapter 5c (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code is filed in court charging the offense as an infraction unless the defendant, at the time he or she is arraigned, after being advised of his or her rights, elects to have the case proceed as a misdemeanor, or

(2) The court, with the consent of the defendant and the prosecution, determines that the offense is an infraction in which event the case shall proceed as if the defendant has been arraigned on an infraction complaint.

(b) Subdivision (a) does not apply to a violation of the code sections listed in subdivisions (c) and (d) if the defendant has had his or her license, registration, or certificate previously revoked or suspended.

(c) The following sections require registration, licensure, certification, or other authorization in order to engage in certain businesses or professions regulated by this code:

(1) Sections 2052 and 2054.
(2) Section 2630.
(3) Section 2903.
(4) Section 3660.
(5) Sections 3760 and 3761.
(6) Section 4080.
(7) Section 4825.
(8) Section 4935.
(9) Section 4980.
(10) Section 4996.
(11) Section 5536.
(12) Section 6704.

(13) Section 6980.10.
(14) Section 7317.
(15) Section 7502 or 7592.
(16) Section 7520.
(17) Section 7617 or 7641.
(18) Subdivision (a) of Section 7872.
(19) Section 8016.
(20) Section 8505.
(21) Section 8725.
(22) Section 9681.
(23) Section 9840.
(24) Subdivision (c) of Section 9891.24.
(25) Section 19049.

(d) Institutions that are required to register with the Bureau for Private Postsecondary and Vocational Education pursuant to Section 94931 of the Education Code.

(e) Notwithstanding any other provision of law, a violation of any of the sections listed in subdivision (c) or (d), which is an infraction, is punishable by a fine of not less than two hundred fifty dollars ($250) and not more than one thousand dollars ($1,000). No portion of the minimum fine may be suspended by the court unless as a condition of that suspension the defendant is required to submit proof of a current valid license, registration, or certificate for the profession or vocation which was the basis for his or her conviction.

SEC. 4. Section 149 of the Business and Professions Code is amended to read:

149. (a) If, upon investigation, an agency designated in subdivision (e) has probable cause to believe that a person is advertising in a telephone directory with respect to the offering or performance of services, without being properly licensed by or registered with the agency to offer or perform those services, the agency may issue a citation under Section 148 containing an order of correction that requires the violator to do both of the following:

(1) Cease the unlawful advertising.

(2) Notify the telephone company furnishing services to the violator to disconnect the telephone service furnished to any telephone number contained in the unlawful advertising.

(b) This action is stayed if the person to whom a citation is issued under subdivision (a) notifies the agency in writing that he or she intends to contest the citation. The agency shall afford an opportunity for a hearing, as specified in Section 125.9.

(c) If the person to whom a citation and order of correction is issued under subdivision (a) fails to comply with the order of correction after

that order is final, the agency shall inform the Public Utilities Commission of the violation and the Public Utilities Commission shall require the telephone corporation furnishing services to that person to disconnect the telephone service furnished to any telephone number contained in the unlawful advertising.

(d) The good faith compliance by a telephone corporation with an order of the Public Utilities Commission to terminate service issued pursuant to this section shall constitute a complete defense to any civil or criminal action brought against the telephone corporation arising from the termination of service.

(e) Subdivision (a) shall apply to the following boards, bureaus, committees, commissions, or programs:

(1) The Bureau of Barbering and Cosmetology.
(2) The Funeral Directors and Embalmers Program.
(3) The Veterinary Medical Board.
(4) The Hearing Aid Dispensers Advisory Commission.
(5) The Landscape Architects Technical Committee.
(6) The California Board of Podiatric Medicine.
(7) The Respiratory Care Board of California.
(8) The Bureau of Home Furnishings and Thermal Insulation.
(9) The Bureau of Security and Investigative Services.
(10) The Bureau of Electronic and Appliance Repair.
(11) The Bureau of Automotive Repair.
(12) The Tax Preparers Program.
(13) The California Architects Board.
(14) The Speech-Language Pathology and Audiology Board.
(15) The Board for Professional Engineers and Land Surveyors.
(16) The Board of Behavioral Sciences.
(17) The State Board for Geologists and Geophysicists.
(18) The Structural Pest Control Board.
(19) The Acupuncture Board.
(20) The Board of Psychology.
(21) The California Board of Accountancy.
(22) The Bureau of Naturopathic Medicine.

SEC. 5. Chapter 8.2 (commencing with Section 3610) is added to Division 2 of the Business and Professions Code, to read:

CHAPTER 8.2. NATUROPATHIC DOCTORS ACT

Article 1. General Provisions

3610. This chapter may be cited as the Naturopathic Doctors Act.

3612. The Bureau of Naturopathic Medicine is hereby created within the Department of Consumer Affairs.

3613. The following definitions apply for the purposes of this chapter:

(a) "Bureau" means the Bureau of Naturopathic Medicine within the Department of Consumer Affairs.

(b) "Naturopathic childbirth attendance" means the specialty practice of natural childbirth by a naturopathic doctor that includes the management of normal pregnancy, normal labor and delivery, and the normal postpartum period, including normal newborn care.

(c) "Naturopathic medicine" means a distinct and comprehensive system of primary health care practiced by a naturopathic doctor for the diagnosis, treatment, and prevention of human health conditions, injuries, and disease.

(d) "Naturopathic doctor" means a person who holds an active license issued pursuant to this chapter.

(e) "Naturopathy" means a noninvasive system of health practice that employs natural health modalities, substances, and education to promote health.

(f) "Prescription drug" means any drug defined by Section 503(b) of the federal Food, Drug and Cosmetic Act (21 U.S.C. Sec. 353) if its label is required to bear the statement "RX only."

3615. The provisions of this chapter are severable. If any provision of this chapter or its application is held invalid, that invalidity shall not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application.

Article 2. Administration

3620. The bureau shall enforce and administer the provisions of this chapter.

3622. The bureau shall adopt regulations in order to carry out the purposes of this chapter.

3623. (a) The bureau shall approve a naturopathic medical education program accredited by the Council on Naturopathic Medical Education or an equivalent federally recognized accrediting body for the naturopathic medical profession that has the following minimum requirements:

(1) Admission requirements that include a minimum of three-quarters of the credits required for a bachelor's degree from a regionally accredited or preaccredited college or university or the equivalency, as determined by the council.

(2) Program requirements for its degree or diploma of a minimum of 4,100 total hours in basic and clinical sciences, naturopathic philosophy, naturopathic modalities, and naturopathic medicine. Of the total requisite hours, not less than 2,500 hours shall consist of academic instruction, and not less than 1,200 hours shall consist of supervised clinical training approved by the naturopathic medical school.

(b) A naturopathic medical education program in the United States shall offer graduate-level full-time studies and training leading to the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine. The program shall be an institution, or part of an institution of, higher education that is either accredited or is a candidate for accreditation by a regional institutional accrediting agency recognized by the United States Secretary of Education and the Council on Naturopathic Medical Education, or an equivalent federally recognized accrediting body for naturopathic doctor education.

(c) To qualify as an approved naturopathic medical school, a naturopathic medical program located in Canada or the United States shall offer a full-time, doctoral-level, naturopathic medical education program with its graduates being eligible to apply to the bureau for licensure and to the North American Board of Naturopathic Examiners that administers the naturopathic licensing examination.

3624. (a) The bureau may grant a certificate of registration to practice naturopathic medicine to a person who does not hold a naturopathic doctor's license under this chapter and is offered a faculty position by the dean of a naturopathic medical education program approved by the bureau, if all of the following requirements are met to the satisfaction of the bureau:

(1) The applicant furnishes documentary evidence that he or she is a United States citizen or is legally admitted to the United States.

(2) The applicant submits an application on a form prescribed by the bureau.

(3) The dean of the naturopathic medical education program demonstrates that the applicant has the requisite qualifications to assume the position to which he or she is to be appointed.

(4) The dean of the naturopathic medical education program certifies in writing to the bureau that the applicant will be under his or her direction and will not be permitted to practice naturopathic medicine unless incident to and a necessary part of the applicant's duties as approved by the bureau.

(b) The holder of a certificate of registration issued under this section shall not receive compensation for or practice naturopathic medicine unless it is incidental to and a necessary part of the applicant's duties in connection with the holder's faculty position.

(c) A certificate of registration issued under this section is valid for two years.

3624.5. (a) This chapter does not apply to a practitioner licensed as a naturopathic doctor in another state or country who meets both of the following requirements:

(1) The practitioner is in consultation with a licensed practitioner of this state, or is an invited guest of any of the following for the purpose of professional education through lectures, clinics, or demonstrations:

(A) The California Medical Association.

(B) The California Podiatric Medical Association.

(C) The California Association of Naturopathic Physicians.

(D) A component county society of subparagraph (A), (B), or (C).

(2) The practitioner does not open an office, appoint a place to meet patients, receive calls from patients, give orders, or have ultimate authority over the care or primary diagnosis of a patient.

3625. (a) The Director of Consumer Affairs shall establish an advisory council consisting of nine members. Members of the advisory council shall include three members who are California licensed naturopathic doctors, or have met the requirements for licensure pursuant to this chapter, three members who are California licensed physicians and surgeons, and three public members.

(b) A member of the advisory council shall be appointed for a four-year term. A person shall not serve as a member of the council for more than two consecutive terms. A member shall hold office until the appointment and qualification of his or her successor, or until one year from the expiration of the term for which the member was appointed, whichever first occurs. Vacancies shall be filled by appointment for unexpired terms. The first terms of the members first appointed shall be as follows:

(1) The Governor shall appoint one physician and surgeon member, one naturopathic doctor member, and one public member, with term expirations of June 1, 2006; one physician and surgeon member with a term expiration date of June 1, 2007, one naturopathic doctor member with a term expiration date of June 1, 2008.

(2) The Senate Rules Committee shall appoint one physician and surgeon member with a term expiration of June 1, 2008, and one public member with a term expiration of June 1, 2007.

(3) The Speaker of the Assembly shall appoint one naturopathic doctor member with a term expiration of June 1, 2007, and one public member with a term expiration of June 1, 2008.

(c) (1) A public member of the advisory council shall be a citizen of this state for at least five years preceding his or her appointment.

(2) A person shall not be appointed as a public member if the person or the person's immediate family in any manner owns an interest in a college, school, or institution engaged in naturopathic education, or the person or the person's immediate family has an economic interest in naturopathy or has any other conflict of interest. "Immediate family" means the public member's spouse, parents, children, or his or her children's spouses.

(d) In order to operate in as cost-effective a manner as possible, the advisory council and any advisory committee created pursuant to this chapter shall meet as few times as necessary to perform its duties, and its members shall receive no compensation, travel allowances, or reimbursement for their expenses.

3626. The Director of Consumer Affairs may employ a bureau chief and other officers and employees as necessary to discharge the duties of the bureau.

3627. (a) The bureau shall establish a naturopathic formulary advisory committee to determine a naturopathic formulary based upon a review of naturopathic medical education and training.

(b) The naturopathic formulary advisory committee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, pharmacists, and naturopathic doctors.

(c) The naturopathic formulary advisory committee shall review naturopathic education, training, and practice and make specific recommendations regarding the prescribing, ordering, and furnishing authority of a naturopathic doctor and the required supervision and protocols for those functions.

(d) The bureau shall make recommendations to the Legislature not later than January 1, 2006, regarding the prescribing and furnishing authority of a naturopathic doctor and the required supervision and protocols, including those for the utilization of intravenous and ocular routes of prescription drug administration. The naturopathic formulary advisory committee and the bureau shall consult with physicians and surgeons, pharmacists, and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

3628. (a) The bureau shall establish a naturopathic childbirth attendance advisory committee to issue recommendations concerning the practice of naturopathic childbirth attendance based upon a review of naturopathic medical education and training.

(b) The naturopathic childbirth attendance advisory committee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, midwives, and naturopathic doctors.

(c) The naturopathic childbirth attendance advisory committee shall review naturopathic education, training, and practice and make specific recommendations to the Legislature regarding the practice of naturopathic childbirth attendance.

(d) The bureau shall make recommendations to the Legislature not later than January 1, 2006. The naturopathic childbirth attendance advisory committee and the bureau shall consult with physicians and surgeons, midwives, and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

Article 3. Licensure

3630. An applicant for a license as a naturopathic doctor shall file with the bureau a written application on a form provided by the bureau, that shows, to the bureau's satisfaction, compliance with all of the following requirements:

(a) The applicant has not committed an act or crime that constitutes grounds for denial of a license under Section 480, and has complied with the requirements of Section 144.

(b) The applicant has received a degree in naturopathic medicine from an approved naturopathic medical school where the degree substantially meets the educational requirements in paragraph (2) of subdivision (a) of Section 3623.

3631. An applicant for licensure shall pass the Naturopathic Physicians Licensing Examination (NPLEX) or an equivalent approved by the North American Board of Naturopathic Examiners. In the absence of an examination approved by the North American Board of Naturopathic Examiners, the bureau may administer a substantially equivalent examination.

3633. The bureau may grant a license to an applicant who is licensed and in good standing as a naturopathic doctor in another state, jurisdiction, or territory in the United States, provided the applicant has met the requirements of Sections 3630 and 3631.

3633.1. The bureau may grant a license to an applicant who meets the requirements of Section 3630, but who graduated prior to 1986, pre-NPLEX, and passed a state naturopathic licensing examination. Applications under this section shall be received no later than December 31, 2007.

3634. (a) A license issued under this chapter shall be subject to renewal biennially as prescribed by the bureau and shall expire unless renewed in that manner. The bureau may provide by regulation for the late renewal of a license.

(b) The holder of a license under this chapter shall be required to take and pass a recertifying examination before the 10th anniversary of his or her initial licensure pursuant to this chapter. On or before July 1, 2010, the bureau shall establish standards for recertification and shall create a recertifying examination or adopt an existing examination that satisfies the recertification standards established by the bureau. In developing standards for recertification, the bureau shall consider information provided by the Council on Naturopathic Medical Education, naturopathic doctors, and other interested parties.

3635. (a) In addition to any other qualifications and requirements for licensure renewal, the bureau shall require the satisfactory completion of 60 hours of approved continuing education biennially. This requirement is waived for the initial license renewal. The continuing education shall meet the following requirements:

(1) At least 20 hours shall be in pharmacotherapeutics.

(2) No more than 15 hours may be in naturopathic medical journals or osteopathic or allopathic medical journals, or audio or videotaped presentations, slides, programmed instruction, or computer-assisted instruction or preceptorships.

(3) No more than 20 hours may be in any single topic.

(4) No more than 15 hours of the continuing education requirements for the specialty certificate in naturopathic childbirth attendance shall apply to the 60 hours of continuing education requirement.

(b) The continuing education requirements of this section may be met through continuing education courses approved by the California Association of Naturopathic Physicians, the American Association of Naturopathic Physicians, the Medical Board of California, the California State Board of Pharmacy, the State Board of Chiropractic Examiners, or other courses approved by the bureau.

3636. (a) Upon a written request, the bureau may grant inactive status to a naturopathic doctor who is in good standing and who meets the requirements of Section 462.

(b) A person whose license is in inactive status may not engage in any activity for which a license is required under this chapter.

(c) A person whose license is in inactive status shall be exempt from continuing education requirements while his or her license is in that status.

(d) To restore a license to active status, a person whose license is in inactive status must fulfill continuing education requirements for the two-year period prior to reactivation, and pay a reactivation fee established by the bureau.

3637. Only an individual may be licensed under this chapter.

Article 4. Application of Chapter

3640. (a) A naturopathic doctor may order and perform physical and laboratory examinations for diagnostic purposes, including, but not limited to, phlebotomy, clinical laboratory tests, speculum examinations, orificial examinations, and physiological function tests.

(b) A naturopathic doctor may order diagnostic imaging studies, including X-ray, ultrasound, mammogram, bone densitometry, and others, consistent with naturopathic training as determined by the bureau, but shall refer the studies to an appropriately licensed health care professional to conduct the study and interpret the results.

(c) A naturopathic doctor may dispense, administer, order, and prescribe or perform the following:

(1) Food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act.

(2) Hot or cold hydrotherapy; naturopathic physical medicine inclusive of the manual use of massage, stretching, resistance, or joint play examination but exclusive of small amplitude movement at or beyond the end range of normal joint motion; electromagnetic energy; colon hydrotherapy; and therapeutic exercise.

(3) Devices, including, but not limited to, therapeutic devices, barrier contraception, and durable medical equipment.

(4) Health education and health counseling.

(5) Repair and care incidental to superficial lacerations and abrasions, except suturing.

(6) Removal of foreign bodies located in the superficial tissues.

(d) A naturopathic doctor may utilize routes of administration that include oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular.

(e) The bureau may establish regulations regarding ocular or intravenous routes of administration that are consistent with the education and training of a naturopathic doctor.

(f) Nothing in this section shall exempt a naturopathic doctor from meeting applicable licensure requirements for the performance of clinical laboratory tests.

(g) The authority to use all routes for furnishing prescription drugs as described in Section 3640.5 shall be consistent with the oversight and supervision requirements of Section 2836.1.

3640.1. The bureau shall make recommendations to the Legislature not later than January 1, 2006, regarding the potential development of scope and supervision requirements of a naturopathic doctor for the

performance of minor office procedures. The bureau shall consult with physicians and surgeons and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

3640.5. Nothing in this chapter or any other provision of law shall be construed to prohibit a naturopathic doctor from furnishing or ordering drugs when all of the following apply:

(a) The drugs are furnished or ordered by a naturopathic doctor in accordance with standardized procedures or protocols developed by the naturopathic doctor and his or her supervising physician and surgeon.

(b) The naturopathic doctor is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the naturopathic doctor, and, where applicable, the facility administrator or his or her designee.

(c) The standardized procedure or protocol covering the furnishing of drugs shall specify which naturopathic doctors may furnish or order drugs, which drugs may be furnished or ordered under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the naturopathic doctor's competence, including peer review, and review of the provisions of the standardized procedure.

(d) The furnishing or ordering of drugs by a naturopathic doctor occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(1) Collaboration on the development of the standardized procedure.

(2) Approval of the standardized procedure.

(3) Availability by telephonic contact at the time of patient examination by the naturopathic doctor.

(e) For purposes of this section, a physician and surgeon shall not supervise more than four naturopathic doctors at one time.

(f) Drugs furnished or ordered by a naturopathic doctor may include Schedule III through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the naturopathic doctor and physician and surgeon and specified in the standardized procedure. When Schedule III controlled substances, as defined in Section 11056 of the Health and Safety Code, are furnished or ordered by a naturopathic doctor, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the

naturopathic doctor's standardized procedure relating to controlled substances shall be provided upon request, to a licensed pharmacist who dispenses drugs, when there is uncertainty about the naturopathic doctor furnishing the order.

(g) The bureau has certified in accordance with Section 2836.3 that the naturopathic doctor has satisfactorily completed adequate coursework in pharmacology covering the drugs to be furnished or ordered under this section. The bureau shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term "furnishing" in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include both of the following:

(1) Ordering a drug in accordance with the standardized procedure.

(2) Transmitting an order of a supervising physician and surgeon.

(i) For purposes of this section, "drug order" or "order" means an order for medication which is dispensed to or for an ultimate user, issued by a naturopathic doctor as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations.

(j) Notwithstanding any other provision of law, the following apply:

(1) A drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician.

(2) All references to prescription in this code and the Health and Safety Code shall include drug orders issued by naturopathic doctors.

(3) The signature of a naturopathic doctor on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

3640.7. Notwithstanding the requirements of Section 3640.5 or any other provision of this chapter, a naturopathic doctor may independently prescribe epinephrine to treat anaphylaxis and natural and synthetic hormones.

3641. (a) A naturopathic doctor shall document his or her observations, diagnosis, and summary of treatment in the patient record. Patient records shall be maintained for a period of not less than seven years following the discharge of the patient. The records of an unemancipated minor shall be maintained until at least one year after the minor has reached 18 years of age or seven years following the discharge of the minor, whichever is longer.

(b) A naturopathic doctor shall have the same authority and responsibility as a licensed physician and surgeon with regard to public health laws, including laws governing reportable diseases and conditions, communicable disease control and prevention, recording

vital statistics, and performing health and physical examinations consistent with his or her education and training.

3642. A naturopathic doctor may not perform any of the following functions:

(a) Prescribe, dispense, or administer a controlled substance or device identified in Sections 801 to 971, inclusive, of Title 21 of the United States Code, except as authorized by this chapter.

(b) Administer therapeutic ionizing radiation or radioactive substances.

(c) Practice or claim to practice any other system or method of treatment beyond that authorized by this chapter, for which licensure is required, unless otherwise licensed to do so.

(d) Administer general or spinal anesthesia.

(e) Perform an abortion.

(f) Perform any surgical procedure.

(g) Perform acupuncture or traditional Chinese and oriental medicine, including Chinese herbal medicine, unless licensed as an acupuncturist as defined in subdivision (c) of Section 4927.

3643. This chapter may not be construed to authorize a naturopathic doctor to practice medicine, as defined under Chapter 5 (commencing with Section 2000), except as specifically authorized in this chapter.

3643.5. (a) This chapter may not be construed to limit the practice of a person licensed, certified, or registered under any other provision of law relating to the healing arts when the person is engaged in his or her authorized and licensed practice.

(b) This chapter may not be construed to limit an activity that does not require licensure or is otherwise allowed by law, including the practice of naturopathy, when performed consistent with Sections 2053.5 and 2053.6.

3644. This chapter does not prevent or restrict the practice, services, or activities of any of the following:

(a) A person licensed, certified, or otherwise recognized in this state by any other law or regulation if that person is engaged in the profession or occupation for which he or she is licensed, certified, or otherwise recognized.

(b) A person employed by the federal government in the practice of naturopathic medicine while the person is engaged in the performance of duties prescribed by laws and regulations of the United States.

(c) A person rendering aid to a family member or in an emergency, if no fee or other consideration for the service is charged, received, expected, or contemplated.

(d) A person who makes recommendations regarding or is engaged in the sale of food, extracts of food, nutraceuticals, vitamins, amino

acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, dietary supplements, and nonprescription drugs or other products of nature, the sale of which is not otherwise prohibited under state or federal law.

(e) A person engaged in good faith in the practice of the religious tenets of any church or religious belief without using prescription drugs.

(f) A person acting in good faith for religious reasons as a matter of conscience or based on a personal belief, while obtaining or providing information regarding health care and the use of any product described in subdivision (d).

(g) A person who provides the following recommendations regarding the human body and its function:

(1) Nonprescription products.

(2) Natural elements such as air, heat, water, and light.

(3) Class I or class II nonprescription, approved medical devices, as defined in Section 360c of Title 21 of the United States Code.

(4) Vitamins, minerals, herbs, homeopathics, natural food products and their extracts, and nutritional supplements.

(h) A person who is licensed in another state, territory, or the District of Columbia to practice naturopathic medicine if the person is incidentally called into this state for consultation with a naturopathic doctor.

(i) A student enrolled in an approved naturopathic medical program whose services are performed pursuant to a course of instruction under the supervision of a naturopathic doctor.

3645. (a) This chapter permits, and does not restrict the use of, the following titles by persons who are educated and trained as any of the following:

(1) "Naturopath."

(2) "Naturopathic practitioner."

(3) "Traditional naturopathic practitioner."

(b) This chapter permits, and does not restrict, the education of persons as described in paragraphs (1) to (3), inclusive, of subdivision (a). Those persons are not required to be licensed under this chapter.

Article 5. Naturopathic Childbirth Attendance

3650. A naturopathic doctor may perform naturopathic childbirth attendance if he or she has completed additional training and has been granted a certificate of specialty practice by the bureau.

3651. In order to be certified for the specialty practice of naturopathic childbirth attendance, a naturopathic doctor shall obtain a passing grade on the American College of Nurse Midwives Written

Examination, or a substantially equivalent examination approved by the bureau, and shall establish, to the bureau's satisfaction, compliance with one of the following requirements:

(a) Successful completion of a certificate of midwifery or naturopathic obstetrics specialty from an approved naturopathic medical education program consisting of not less than 84 semester units or 126 quarter units that substantially complies with the following educational standards and requirements:

(1) The curriculum is presented in semester or quarter units under the following formula:

(A) One hour of instruction in the theory each week throughout a semester or quarter equals one unit.

(B) Three hours of clinical practice each week throughout a semester or quarter equals one unit.

(2) The program provides both academic and clinical preparation that is substantially equivalent to that provided in a program accredited by the American College of Nurse Midwives. The program includes, but is not limited to, preparation in all of the following areas:

(A) The art and science of midwifery, one-half of which shall be in theory and one-half of which shall be in clinical practice. Theory and clinical practice shall be concurrent in the areas of maternal and child health, including, but not limited to, labor and delivery, neonatal well care, and postpartum care.

(B) Communications skills that include the principles of oral, written, and group communications.

(C) Anatomy and physiology, genetics, obstetrics and gynecology, embryology and fetal development, neonatology, applied microbiology, chemistry, child growth and development, pharmacology, nutrition, laboratory diagnostic tests and procedures, and physical assessment.

(D) Concepts in psychosocial, emotional, and cultural aspects of maternal and child care, human sexuality, counseling and teaching, maternal and infant and family bonding process, breast feeding, family planning, principles of preventive health, and community health.

(E) Aspects of the normal pregnancy, labor and delivery, postpartum period, newborn care, family planning, or routine gynecological care in alternative birth centers, homes, and hospitals.

(3) The program integrates the following subjects throughout its entire curriculum:

(A) Midwifery process.

(B) Basic intervention skills in preventive, remedial, and supportive midwifery.

(C) The knowledge and skills required to develop collegial relationships with health care providers from other disciplines.

(D) Related behavioral and social sciences with emphasis on societal and cultural patterns, human development, and behavior related to maternal and child health, illness, and wellness.

(4) Instruction in personal hygiene, client abuse, cultural diversity, and the legal, social, and ethical aspects of midwifery.

(5) Instruction in the midwifery management process which shall include all of the following:

(A) Obtaining or updating a defined and relevant database for assessment of the health status of the client.

(B) Identifying problems based upon correct interpretation of the database.

(C) Preparing a defined needs or problem list, or both, with corroboration from the client.

(D) Consulting, collaborating with, and referring to, appropriate members of the health care team.

(E) Providing information to enable clients to make appropriate decisions and to assume appropriate responsibility for their own health.

(F) Assuming direct responsibility for the development of comprehensive, supportive care for the client and with the client.

(G) Assuming direct responsibility for implementing the plan of care.

(H) Initiating appropriate measures for obstetrical and neonatal emergencies.

(I) Evaluating, with corroboration from the client, the achievement of health care goals and modifying the plan of care appropriately, or

(b) Successful completion of an educational program that the bureau has determined satisfies the criteria of subdivision (a) and current licensure as a midwife by a state with licensing standards that have been found by the bureau to be substantially equivalent to those adopted by the bureau pursuant to this article.

3651.5. A naturopathic doctor certified for the specialty practice of naturopathic childbirth attendance shall do both of the following:

(a) Maintain current certification in neonatal resuscitation and cardiopulmonary resuscitation.

(b) File with the bureau a written plan for the following:

(1) Consultation with other health care providers.

(2) Supervision by a licensed physician and surgeon who has current practice or training in obstetrics to assist a woman in childbirth so long as progress meets criteria accepted as normal. The plan shall provide that all complications shall be referred to a physician and surgeon immediately.

(3) Emergency transfer and transport of an infant or a maternity patient, or both, to an appropriate health care facility, and access to

neonatal intensive care units and obstetrical units or other patient care areas.

3652. (a) A certificate of specialty practice in naturopathic childbirth attendance shall expire concurrently with the licensee's naturopathic doctor's license.

(b) The certificate may be renewed upon submission of the renewal fee set by the bureau and evidence, to the bureau's satisfaction, of the completion of 30 hours of continuing education credits in naturopathic childbirth, midwifery, or obstetrics. Fifteen hours may be applied to the 60 hours of continuing education required for naturopathic doctors.

(c) Licensing or disciplinary action by the bureau or a judicial authority shall be deemed to have an equal effect upon the specialty certificate to practice naturopathic childbirth issued to a licensee, unless otherwise specified in the licensing or disciplinary action. When the subject of a licensing or disciplinary action relates specifically to the practice of naturopathic childbirth by a licensee holding a specialty certificate, the action may, instead of affecting the entire scope of the licensee's practice, suspend, revoke, condition, or restrict only the licensee's authority under the specialty certificate.

3653. (a) Naturopathic childbirth attendance does not include the use or performance of any of the following:

(1) Forceps delivery.

(2) General or spinal anesthesia.

(3) Cesarean section delivery.

(4) Episiotomies, except to the extent that they meet the same supervision requirements set forth in Section 2746.52.

(b) Naturopathic childbirth attendance does not mean the management of complications in pregnancy, labor, delivery, or the neonatal period. All complications shall be referred to an obstetrician or other licensed physician and surgeon as appropriate.

3654. In addition to Section 3640, a naturopathic doctor who holds a specialty certificate in naturopathic childbirth attendance may administer, order, or perform any of the following:

(a) Postpartum antihemorrhagic drugs.

(b) Prophylactic opthalmic antibiotics.

(c) Vitamin K.

(d) RhoGAM.

(e) Local anesthetic medications.

(f) Intravenous fluids limited to lactated ringers, 5 percent dextrose with lactated ringers, and heparin and 0.9 percent sodium chloride for use in intravenous locks.

(g) Epinephrine for use in maternal anaphylaxis pending emergency transport.

(h) Measles, mumps, and rubella (MMR) vaccine to nonimmune, nonpregnant women.

(i) HBIG and GBV for neonates born to hepatitis B mothers, per current Centers for Disease Control guidelines.

(j) Antibiotics for intrapartum prophylaxis of Group B Betahemolytic Streptococcus (GBBS), per current Centers For Disease Control guidelines.

(k) Equipment incidental to the practice of naturopathic childbirth, specifically, dopplers, syringes, needles, phlebotomy equipment, suture, urinary catheters, intravenous equipment, amnihooks, airway suction devices, neonatal and adult resuscitation equipment, glucometer, and centrifuge.

(*l*) Equipment incidental to maternal care, specifically, compression stockings, maternity belts, breast pumps, diaphragms, and cervical caps.

3655. (a) A licensee holding a speciality certificate in naturopathic childbirth attendance shall disclose to each client, in writing, the following:

(1) The qualifications and credentials of the naturopathic doctor.

(2) A copy of the written plan for consultation, emergency transfer, and transport.

(3) A description of the procedures, benefits, and risks of birth in the home or outside of a hospital setting.

(4) The status of liability coverage of the licensee for the practice of naturopathic childbirth attendance.

(b) The form must be signed by the client, filed in the client's chart, and a copy given to the client.

Article 6. Offenses and Enforcement

3660. Except as provided in subdivision (h) of Section 3644, a person shall have a valid, unrevoked, or unsuspended license issued under this chapter to do any of the following:

(a) To claim to be a naturopathic doctor, licensed naturopathic doctor, doctor of naturopathic medicine, doctor of naturopathy, or naturopathic medical doctor.

(b) To use the professional abbreviation "N.D." or other titles, words, letters, or symbols with the intent to represent that he or she practices, is authorized to practice, or is able to practice naturopathic medicine as a naturopathic doctor.

3661. A naturopathic doctor who uses the term or designation "Dr." shall further identify himself or herself as "Naturopathic Doctor," "Licensed Naturopathic Doctor," "Doctor of Naturopathic Medicine," or "Doctor of Naturopathy" and shall not use any term or designation

that would tend to indicate the practice of medicine, other than naturopathic medicine, unless otherwise licensed as a physician and surgeon, osteopathic doctor, or doctor of chiropractic.

3662. It shall constitute unprofessional conduct for a naturopathic doctor to violate, attempt to violate, assist in the violation of, or conspire to violate, any provision or term of this chapter or any regulation adopted under it.

3663. The bureau may discipline a naturopathic doctor for unprofessional conduct. After a hearing conducted in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code), the bureau may deny, suspend, revoke, or place on probation the license of, or reprimand, censure, or otherwise discipline a naturopathic doctor in accordance with Division 1.5 (commencing with Section 475).

3664. A person who violates Section 3660 or 3661 is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not more than five thousand dollars ($5,000), or by imprisonment of not more than one year in a county jail, or by both that fine and imprisonment.

Article 7. Naturopathic Corporations

3670. A naturopathic corporation is a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, if the corporation and its shareholders, officers, directors, and employees rendering professional services who are naturopathic doctors are in compliance with the Moscone-Knox Professional Corporation Act (Part 4 (commencing with Section 13400) of Division 3 of Title 1 of the Corporations Code), this chapter, and all other statutes and regulations now or hereafter enacted or adopted pertaining to that corporation and the conduct of its affairs. With respect to a naturopathic corporation, the governmental agency referred to in the Moscone-Knox Professional Corporation Act is the bureau.

3671. A naturopathic corporation shall not engage in any conduct that constitutes unprofessional conduct. In the conduct of its practice, the naturopathic corporation shall comply with statutes and regulations to the same extent as an individual holding a license under this chapter.

3672. The income of a naturopathic corporation attributable to professional services rendered while a shareholder is a disqualified person, as defined in Section 13401 of the Corporations Code, shall not in any manner accrue to the benefit of the shareholder or his or her shares in the naturopathic corporation.

3673. Except as provided in Section 13403 of the Corporations Code, each director, shareholder, and officer of a naturopathic corporation, except an assistant secretary and an assistant treasurer, shall be a licensed person as defined by Section 13401 of the Corporations Code.

3674. The name of a naturopathic corporation and any name or names under which it may render professional services, shall contain the words "naturopathic" or "naturopathic doctor" and, as appropriate, wording or abbreviations denoting its status as a corporation.

3675. The bureau may adopt and enforce regulations to carry out the purposes and objectives of this article, including, but not limited to, regulations requiring the following:

(a) That the bylaws of a naturopathic corporation include a provision whereby the capital stock of the corporation owned by a disqualified person, as defined in Section 13401 of the Corporations Code, or a deceased person, shall be sold to the corporation or to the remaining shareholders of the corporation within any time as the regulations may provide.

(b) That a naturopathic corporation shall provide adequate security by insurance or otherwise for claims against it by its patients arising out of the rendering of professional services.

Article 8. Fiscal Administration

3680. The bureau shall establish the amount of the fee assessed to conduct activities of the bureau, including the amount of fees for applicant licensure, licensure examination, licensure renewal, late renewal, and childbirth certification.

3681. (a) All fees collected by the bureau shall be paid into the State Treasury and shall be credited to the Naturopathic Doctor's Fund which is hereby created in the State Treasury. The money in the fund shall be available to the bureau for expenditure for the purposes of this chapter only upon appropriation by the Legislature.

(b) Notwithstanding subdivision (a), all money other than revenue described in Section 207 received and credited to the Naturopathic Doctor's Fund in the 2003–04 fiscal year is hereby appropriated to the bureau for the purpose of implementing this chapter.

Article 9. Miscellaneous Provisions

3685. (a) The provisions of Article 8 (commencing with Section 3680) shall become operative on January 1, 2004, but the remaining provisions of this chapter shall become operative on July 1, 2004. It is

the intent of the Legislature that the initial implementation of this chapter be administered by fees collected in advance from applicants. Therefore, the bureau shall have the power and authority to establish fees and receive applications for licensure or intents to file application statements on and after January 1, 2004. The department shall certify that sufficient funds are available prior to implementing this chapter. Funds from the General Fund may not be used for the purpose of implementing this chapter.

(b) This chapter shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute that is enacted before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this chapter renders the bureau subject to the review required by Division 1.2 (commencing with Section 473).

(c) The bureau shall prepare the report required by Section 473.2 no later than September 1, 2007.

SEC. 6. Section 13401.5 of the Corporations Code is amended to read:

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation:

(a) Medical corporation.

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(b) Podiatric medical corporation.

(1) Licensed physicians and surgeons.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(c) Psychological corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed chiropractors.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(g) Marriage and family therapy corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.

(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(*l*) Acupuncture corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.

(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.
(9) Licensed marriage, family, and child counselors.
(10) Licensed clinical social workers.
(11) Licensed optometrists.

SEC. 7. Section 13401.5 of the Corporations Code is amended to read:

13401.5. Notwithstanding subdivision (d) of Section 13401 and any other provision of law, the following licensed persons may be shareholders, officers, directors, or professional employees of the professional corporations designated in this section so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the professional corporation so designated herein, and so long as the number of those licensed persons owning shares in the professional corporation so designated herein does not exceed the number of persons licensed by the governmental agency regulating the designated professional corporation:

(a) Medical corporation.
(1) Licensed doctors of podiatric medicine.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(b) Podiatric medical corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(c) Psychological corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Registered nurses.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.

(7) Licensed chiropractors.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(d) Speech-language pathology corporation.
(1) Licensed audiologists.
(e) Audiology corporation.
(1) Licensed speech-language pathologists.
(f) Nursing corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Licensed optometrists.
(5) Licensed marriage and family therapists.
(6) Licensed clinical social workers.
(7) Licensed physician assistants.
(8) Licensed chiropractors.
(9) Licensed acupuncturists.
(10) Naturopathic doctors.
(g) Marriage and family therapy corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed clinical social workers.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(h) Licensed clinical social worker corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Licensed marriage and family therapists.
(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(i) Physician assistants corporation.
(1) Licensed physicians and surgeons.
(2) Registered nurses.
(3) Licensed acupuncturists.
(4) Naturopathic doctors.
(j) Optometric corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.

(4) Registered nurses.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Naturopathic doctors.
(k) Chiropractic corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed acupuncturists.
(9) Naturopathic doctors.
(*l*) Acupuncture corporation.
(1) Licensed physicians and surgeons.
(2) Licensed doctors of podiatric medicine.
(3) Licensed psychologists.
(4) Registered nurses.
(5) Licensed optometrists.
(6) Licensed marriage and family therapists.
(7) Licensed clinical social workers.
(8) Licensed physician assistants.
(9) Licensed chiropractors.
(10) Naturopathic doctors.
(m) Naturopathic doctor corporation.
(1) Licensed physicians and surgeons.
(2) Licensed psychologists.
(3) Registered nurses.
(4) Licensed physician assistants.
(5) Licensed chiropractors.
(6) Licensed acupuncturists.
(7) Licensed physical therapists.
(8) Licensed doctors of podiatric medicine.
(9) Licensed marriage, family, and child counselors.
(10) Licensed clinical social workers.
(11) Licensed optometrists.
(n) Dental corporation.
(1) Licensed physician and surgeons.
(2) Dental assistants.
(3) Registered dental assistants.
(4) Registered dental assistants in extended functions.
(5) Registered dental hygienists.

(6) Registered dental hygienists in extended functions.

(7) Registered dental hygienists in alternative practice.

SEC. 8. Section 7 of this bill incorporates amendments to Section 13401.5 of the Corporations Code proposed by both this bill and AB 123. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2004, (2) each bill amends Section 13401.5 of the Corporations Code, and (3) this bill is enacted after AB 123, in which case Section 6 of this bill shall not become operative.

SEC 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AGENDA ITEM F

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: February 28, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Implementation of SB 151 (Chapter 406, Statutes of 2003) Requirements for Prescribing and Dispensing Controlled Substances**

As of January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have been printed by a board-approved printer and must contain specific elements. There is no specific format, size or color for the security prescription forms, so pharmacists need to be aware of the required elements.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that a board-approved printer did not print it. Such prescriptions should be reported to the BNE at (916) 319-9062.

In summary the changes that take effect January 1, 2005 are:

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions must be on the new controlled substance prescription forms printed by an "approved" printer (oral and fax orders for Schedules III-V are still permitted).
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2). (This exemption doesn't apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, the board prepared a series of articles that appeared in the January newsletter and on the board's Web site. Another series of questions has also been prepared that will be added to the board's Web site.

A question that is not on this recent updated series of questions but was asked at a recent SB 151 presentation is regarding prescriptions for Schedule III-V medications that are not on the new security forms. The board's direction to pharmacies is to treat these prescriptions as "oral" prescriptions and for the pharmacist to initial and date under Health and Safety Code 11164(b)(1). The pharmacist should always use his or her professional judgment when filling the prescription, contact the prescriber to verify if necessary and to advise the prescriber that for future written prescriptions, security forms are required.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

PREPRINTED PRESCRIBER REQUIREMENTS FOR CONTROLLED SUBSTANCE PRESCRIPTION FORMS AND LIMITED EXCEPTIONS FOR LICENSED HEALTH CARE FACILITIES THAT COMPUTER GENERATE PRESCRIPTIONS

Preprinted Prescriber Information —Controlled substance security prescription forms must be preprinted with the name, category of licensure (e.g., MD, DDS, etc), license number, and federal controlled substance registration number of the prescriber, by a board-approved security printer. In addition, the prescriber's address and phone number is required to be on the form to be a valid prescription; therefore, the board recommends this information be preprinted as well. However, locum tenens physicians or other physicians that substitute at various facilities may opt to not preprint the address and phone number, but instead stamp or handwrite this information at the time the prescription is written. Multiple prescribers, even multiple addresses, with check boxes are allowed on the controlled substance prescription forms. *(Health and Safety Code section 11162.1[a][9] and 11164)*

Preprinted Forms for Licensed Health Care Facilities - The "institution" style form is an option available to licensed health care facilities only. A "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with section 1250) of Chapter 2 of Division 2 of the California Health and Safety Code, such as, an inpatient acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility. Qualified licensed health care facilities that wish to use the "institution" style forms, must designate a prescriber to order forms, receive delivery, distribute the forms to authorized prescribers within the facility, and record the names, federal controlled substance registration numbers, license numbers, and quantity of forms issued to each (see a limited exception below). The facility must maintain the records for three years. Institution style forms may be filled at any pharmacy.

- **Controlled Substance Prescription Forms for Institutional Use**— The institutional style forms must be ordered from an approved printer and include all of the required security features. The "designated prescriber's" name, category of licensure, license number, and federal controlled substance registration number must be preprinted on the institution style form, as well as, the facility's name, address, and Department of Health Services issued license number. A blank area is provided for the actual prescriber within the facility to write or stamp his or her name, category of licensure, license number, and federal controlled substance registration number when the prescription is written. It is important to note that a prescription written on an institutional style form is not valid without the actual prescriber information filled in on the form. *(Health and Safety Code section 11162.1[c])*

  a) **Computer Generated Prescriptions Using "Institution" Style Controlled Substance Prescription Forms –** A special provision for licensed health care facilities that computer generate prescriptions to print on "institution" style forms on a shared laser or dot matrix printer have the following exceptions: *(Health and Safety Code section 11162.1[c][4][B])*

  - Computer generated institution style forms do not require the quantity check-off boxes;
  - The facility's "designated prescriber" is not required to maintain a record of the prescriber's to whom the institution style computer-generated prescription forms are distributed to within the facility; and
  - The computer software can generate the actual prescriber's name, category of licensure, federal controlled substance registration number, and license number on the form, as well as, the date the prescription is written to print on the laser or dot matrix institution form.

  Note: these exceptions do not apply to laser or dot matrix style controlled substance prescription forms for use by a prescriber, group practice, clinic, or any other outpatient setting.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Even More SB 151 Questions and Answers

Q Can a pharmacist fill multiple controlled substance prescriptions for the same drug written on one prescription form; one prescription to fill immediately, the rest include instructions to fill after a specific date?

A No, not if the prescriptions are all written on the same prescription form. However, a pharmacist can fill a prescription written for one or more controlled substances properly dated with the date written by the prescriber, which includes instructions to fill at future date. All controlled substance prescriptions are valid for six months from the date written. Each prescription with a future fill date must be written on a separate prescription form.

Q Can a pharmacist fill a prescription after January 1, 2005, for a Schedule II medication written before January 1, 2005 on a triplicate prescription?

A Yes. Prior to January 1, 2005, Schedule II medications could be written on either the new tamper resistant prescription form or a triplicate prescription form. All controlled substance prescriptions are valid for six months from the date written.
(Health and Safety Code section 11166)

Q Can a pharmacist fill a prescription after January 1, 2005, for a Schedule III through V medication on a regular plain prescription form that was written before January 1, 2005?

A Yes. Prior to January 1, 2005, Schedule III through V medications could be written on a plain prescription form. All controlled substance prescriptions are valid for six months from the date written. (Health and Safety Code section 11166)

Q Can a pharmacist fill a prescription for a Schedule III through V medication, written after January 1, 2005, on a regular plain prescription using the emergency fill provisions of Health and Safety Code section 11167?

A Yes, however, prescribers are encouraged to phone or fax Schedule III through V prescriptions if they have not yet received their new prescription forms or if they run out of the forms temporarily. However, in some circumstances phoning or faxing may not be a viable option, therefore, pharmacies may receive a Schedule III through V prescription with the notation "11167 exemption". In these cases, pharmacists should use their professional judgment when filling the prescription, contact the prescriber to verify if necessary, and sign and date the prescription.

Q After January 1, 2005, what should prescribers do with their unused triplicate prescription forms?

A The Department of Justice issued the triplicate prescription forms with an expiration date at the bottom of the form. The Department of Justice is requesting that unused triplicate forms be disposed of as follows:

- If it is past the expiration date on the triplicate forms then the unused triplicates can be shredded.
- If it is not past the expiration date, please return the unused triplicates to the Department of Justice, CURES Program, 4949 Broadway, Sacramento, California 95820 by certified or registered mail for destruction.

For more information, please call the CURES Program at (916) 319-9062.

Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants

Q Is the supervising physician information for a controlled substance prescription written by a nurse practitioner, certified nurse midwife, or physician assistant required to be on the prescription label?

A No, only the information for the nurse practitioner, certified nurse midwife, or physician assistant that signed the prescription is required to be printed on the prescription label. (Business and Professions Code section 4076 [a][4])

Q Can a nurse practitioner or certified nurse midwife stamp or handwrite their name, category of licensure, DEA registration number, and furnishing number on their supervising physician's preprinted controlled substance prescription pad to write a controlled substance drug order?

A No. The law requires that the prescriber's (i.e., nurse practitioner or certified nurse midwife) name, category of licensure, DEA registration number, and furnishing number be preprinted on the new controlled substance prescription forms by a board-approved security printer. (Health and Safety Code section 11162.1 [a][9])

Q Is a supervising physician's name, DEA registration number, and license number required to also be printed on a nurse practitioner's or certified nurse midwife's preprinted controlled substance prescription form?

A No, the supervising physician information is no longer required to be on the nurse practitioner's or certified nurse midwife's controlled substance prescription form. (Business and Professions Code section 2836.1 [f] & [I])

Q Can a physician assistant stamp or handwrite their name, category of licensure, DEA registration number, and license number on their supervising physician's preprinted controlled substance prescription pad to write a controlled substance prescription/drug order?

A No. The law requires that the prescriber's (i.e., physician assistant) name, category of licensure, DEA registration number, and license number be preprinted on the new controlled substance prescription forms by a board-approved security printer. (Health and Safety Code section 11162.1 [a][9])

Q Is a supervising physician's name, DEA registration number, and license number required to be printed on a physician assistant's preprinted controlled substance prescription form?

A Yes. The law requires that a physician assistant authorized to write controlled substance drug orders pursuant to authority granted to them by their supervising physician and DEA registration, must have their supervising physician's name, DEA registration number, address, and telephone number preprinted on the physician assistant's preprinted controlled substance prescription form. (Business and Professions Code section 3502.1 [b] & [d] and Health and Safety Code section 11162.1[a][9])

Licensed Health Care Facilities

Q What is an "institution" form for a qualified licensed health care facility?

A A licensed health care facility (defined below) has the option of using an "institution" style controlled substance prescription form. In order to use the "institution" form, the licensed health care facility must designate a prescriber to represent the facility. The "designated prescriber's" name, state license number, category of licensure, and DEA number are preprinted on the "institution" style prescription blank along with the facility name, address, and Department of Health Services license number. The "institution" style form also includes a blank space for the actual prescriber within the facility to handwrite, print, or stamp his or her name, state license number, category of licensure, and DEA registration number when writing the prescription.

The institution forms are delivered to the designated prescriber who is responsible for distributing the prescription blanks to authorized prescribers within the facility. The "designated prescriber" must maintain a record that includes the name, category of licensure, state license number, DEA registration number, and the quantity of "institution" forms issued to each prescriber within the facility and maintain the record in a readily retrievable format for 3 years. The board recommends that the designated prescriber also record the batch/lot numbers of the institution forms distributed. (Health & Safety Code section 11162.1[c])

Q Does my facility qualify as a "licensed health care facility" so that we can order "institution" style controlled substance prescription forms?

A "Licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with section 1250) of Chapter 2 of Division 2 of the California Health and Safety Code, such as, a general 24-hour acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility.

Laser or Dot Matrix Style Controlled Substance Prescription Forms

Q Can a licensed health care facility computer generate "institution" style controlled substance prescriptions to print on a shared laser or dot matrix printer within the facility?

A Yes, a licensed health care facility (defined above) can purchase specially designed "institution" style prescription blanks that can be used when computer generating prescriptions to print on a shared laser or dot matrix printer within the facility. These "institution" style laser or dot matrix forms must adhere to all of the provisions outlined above for "institution" style forms; including preprinting the designated prescriber's information and incorporating the required security features pursuant to Health and Safety Code section 11162.1 et seq. However, the following limited provisions were added to subparagraph (c), as a result of Assembly Bill 30 (Richman, Statues of 2004), specifically for licensed health care facilities that computer generate prescriptions using an "institution" style prescription form to print on a shared laser or dot matrix printer:

- Computer generated "institution" style laser or dot matrix prescription forms do not require the quantity check off boxes;
- The facility's "designated prescriber" is not required to maintain a record of the prescribers to whom the institution style computer generated laser or dot matrix printer prescription forms are distributed to within the facility; and
- In addition to the patient and prescription information, the computer software can generate the actual prescriber's name, category of licensure, DEA registration number, and license number, as well as, the date the prescription is written, to print on the "institution" style laser or dot matrix prescription form.

Note: these exceptions do <u>not</u> apply to laser or dot matrix style controlled substance prescription forms for use by an individual prescriber, group practice, clinic, or any other outpatient setting.

Q Can a prescriber purchase stock prescription blanks for a laser printer or dot matrix printer that comes with all of the security features <u>except</u> for the preprinted prescriber name, category of licensure, DEA number, and state license number to computer generate prescriptions?

A No, the preprinted prescriber information is one of the security features and therefore, must be preprinted by an approved security printer. However, a prescriber can purchase security prescription blanks from an approved printer that are designed for laser and dot matrix printers. The laser or dot matrix printer security prescription blanks must come preprinted with the prescriber name, category of licensure, DEA registration number and license number and contain all of the required security features in Health and Safety Code section 11162.1 et seq. The prescriber could then computer generate the patient and prescription information to print on the laser or dot matrix printer security prescription blank. The prescriber must the sign and date the prescription in ink. Note: Not all approved security printers offer this type of form. (Health and Safety Code section 11162.1 et seq. and 11164)

CURES Reporting

Q Is it true that pharmacies must now report Schedule III, in addition to Schedule II, prescriptions filled to CURES?

A Yes, effective January 1, 2005, all pharmacies are now required to submit prescription information for all Schedule II and III prescriptions filled to CURES. Pharmacies must contact the data collection vendor, Atlantic Associates at 888-492-7341 for data submission instructions and data field specifications. Click here for blank transmittal forms, reporting requirements, and data field specifications. (Health and Safety Code section 11165)

Q Do hospital pharmacies report both inpatient chart orders and outpatient discharge prescriptions for Schedule II and III medications to CURES?

A Hospital pharmacies must report all Schedule II and III outpatient or discharge prescriptions filled, including any Schedule II or III medications provided by an emergency room physician to a patient discharged from the emergency room when the hospital pharmacy is closed. Hospital pharmacies are not required to report inpatient chart ordered medications. Hospital pharmacies must contact the data collection vendor, Atlantic Associates, at 888-492-7341 for data submission instructions and data field specifications. Click here for blank transmittal forms, reporting requirements, and data field specifications. (Business and Profession Code section 4068 (new), Health and Safety Code section 11165, and California Code of Regulations section 1715.5)

Q I am a prescriber (i.e., physician, dentist, veterinarian, osteopathic physician, podiatrist, optometrist, etc.) that dispenses Schedule II and/or III medications directly to my patients from my office, do I have to report the dispensing information to CURES?

A Yes. Dispensing prescribers must report monthly to the Department of Justice, Bureau of Narcotic Enforcement, CURES Program, the dispensing information of any Schedule II or III drug dispensed directly to a patient by the prescriber. Reporting forms, requirements, and instructions can be found on the Department of Justice website at http://www.ag.ca.gov/bne/content/trips.htm. (Health and Safety Code section 11190[c])

AGENDA ITEM G

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: February 28, 2005

From: Patricia F. Harris
Executive Officer

Subject: SB 1307 (Figueroa)
Chapter 857, Statutes of 2004

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight will be pedigree requirement. The bill requires an electronic pedigree by January 1, 2006 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States. The new requirements are as follows:

Electronic Pedigree for Dangerous Drugs (New)
B&PC 4034—requires an electronic "pedigree" by January 1, 2007. Said pedigree will contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.
The pedigree must contain all of the following information: (1) the source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source (2) the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers (3) the business name, address, and if appropriate, the state license number, including a California license number if available, each owner of the dangerous drug and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug (4) a certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.
The application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008.

Pedigree Required (New)

B&PC 4163— presently allow manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)
B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)
B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009

It is anticipated that Radio Frequency Identification technology (RFID) will the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

At the April board meeting, Acerity Corporation will present its security software program, which is an electronic authentication process. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications. At the last enforcement committee meeting, there was a presentation by T3Ci. As stated with that presentation, it is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

At the invitation of the National Association of Boards of Pharmacy (NABP), California participated on its task force to develop recommendations for electronic pedigree requirements. The recommendations of the task force will be made public in early March. Again at the invitation of NABP, California has participated in two wholesale distributors regulatory meetings. The purpose of the these meetings is to work with the industry to established the prescription drug pedigree requirements so that the industry can identify its business solutions and technology standards to capture the pedigree data.

Acerity
Corporation

Company Overview

Acerity Corporation collaborates with customers to develop and deploy solutions to expose, intercept and deter counterfeits to:

- Protect Your Company Image
- Protect Consumers
- Reduce Losses and Fines
- Enhance Homeland Security (for government applications)

We implement our patent pending AuthentiTrak™ process for:

- Covert product authentication applications
- Proactive supply chain item authentication and verification
- Authentication and verification of documents, including travel documents, ID cards, etc.

The AuthentiTrak™ process is "self sufficient" where the checking of authenticity does not require database access for individual verification. With the use of proven cryptography techniques, similar to those for electronic credit card transactions, the AuthentiTrak™ process is secure. AuthentiTrak™'s strengths allow a broad spectrum of cost effective applications.

Acerity Corporation • 46687 Paseo Padre Pkwy • Fremont, CA 94539
510 - 673 - 5994 • sales@acerity.com • www.acerity.com

Acerity Corporation

Technology Overview

AuthentiTrak™

Acerity's security software deploys AuthentiTrak™ (patent pending), which is a "self sufficient" electronic authentication process. AuthentiTrak™ employs proven cryptography techniques in conjunction with Radio Frequency Identification (RFID) forming a multilayer secure process which provides numerous advantages and allows versatile and cost effective applications that other approaches do not have.

- **Self Sufficiency** - sufficient item and security data are stored in the RFID tag such that the RFID tag has sufficient information for identifying the item and for authenticity verification of the item. This capability allows cost effective solutions and avoids the need of company data going beyond the corporate boundary for applications (for example, pharmaceutical supply chain authentication application) which need to verify source against item flow path.
- **Versatile robust electronic approach** - compared to mechanical, chemical and optical approaches, Acerity's electronic authentication schema is secure. Encryption keys can be changed periodically, with zero cost-of-change, making it virtually impossible for the counterfeiters to keep up. You change your key rather than change your process. It is painless and transparent to your operations.
- **Significant cost avoidance in information infrastructure** - our competitors' electronic authentication solutions typically use approaches requiring database access on each verification of the item's authenticity. If you are the party authenticating the product, you have the huge burden of providing information services to others who have to verify the item. The magnitude of your burden relates to your item production rate and the number of verifications required throughout the life of each item. Also, the information services that you have to provide are mission critical to your clients and your distribution / sales channels. Using Acerity's solution you do not have that burden and yet the authentication process is robust and secure.
- **Cost effectively addressing the package reuse exposure** - it is expected that resourceful counterfeiters can gather and reuse authentic packages for fake products. With Acerity's solution deployed either as a covert authentication solution or as a supply chain authentication solution it is extremely difficult and economically unattractive for counterfeiters to reuse authentic packages.

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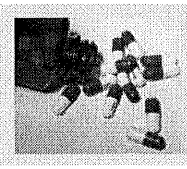
Corporation

AuthentiTrak™ :: Covert



AuthentiTrak™::Covert is an advanced electronic covert authentication solution. Unlike the traditional approaches using chemical, optical or physical means, AuthentiTrak™::Covert is secure and cannot be compromised. It is based on Radio Frequency Identification (RFID) and proven cryptography techniques. The authenticity verification "self sufficiency" results in a cost effective solution that is easy to implement.

Constant changes are usually required in order to ensure that counterfeiters cannot keep up. With this covert solution, the constant changes are automatically performed and no process change is required.

This solution offers:

- Ease of use
- Has zero cost-of-change to ensure ongoing updates ahead of counterfeiters
- Ongoing automatic updates which are totally transparent to your operations
- Protection of your brand name and company image.

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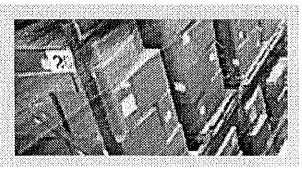
Acerity
Corporation

AuthentiTrak™ :: Supply Chain



The AuthentiTrak™::Supply Chain solution is for deployment in the whole supply chain as a proactive vehicle for combating counterfeits.

Acerity's supply chain solution:

- **Exposes counterfeits -** at any point in the supply chain if an item does not have a verifiable source or a source record which fails verification, the questionable nature of the item is exposed.

- **Intercepts counterfeits -** when an item is exposed as questionable it will not be accepted by any party downstream in the supply chain.

- **Deters counterfeiting -** authorized parties can request prove-of-source records from all the parties through whom the item passed and from the prove-of-source records AuthentiTrak™ can recreate the path of the item and identify the culprit.

- **Eliminates the issue of data custodian -** AuthentiTrak™'s "self sufficiency" in authenticity verification makes it possible to keep your data within your corporate boundary, eliminates the issue of data custodian and yet achieve reliable authentication. For some anti-counterfeit applications, for example, that in the supply chain for pharmaceutical products, as a participant in the supply chain you have to submit all your item flow transactions (where you obtained the item and where you shipped the item) to a data custodian. This has to be done because in those applications, in addition to the verification of the item's authenticity, the consistency of the source of the item against its flow paths have to be verified too to ensure that the item had not been infiltrated from questionable source.

- **AuthentiTrak™ effectively supports repackaging** - AuthentiTrak™ supports repackaging without compromising its abilities to authenticate and verify. For some industries the repackaging of products in the supply chain is inevitable.

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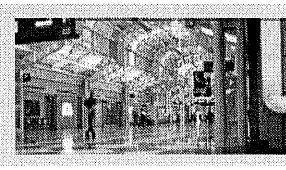
Corporation

AuthentiTrak™ ::Travel



AuthentiTrak™::Travel is designed and developed based on country governments' inputs and requirements addressing their needs in processing visitors and enhancing security resulting in a comprehensive solution facilitating the country government to:

- Identify visitors by using Radio Frequency Identification (RFID) on the travel document
- Track the visitor's entrance and exit of the country
- Make possible timely informed decision on travel visa issuance
- Facilitate effective security alerts and the use of "Black List"
- Identify overstays
- Keep easily retrievable records on visitors:
    - Connect, in a real-time basis, their Consulates, which issues visas
    - Port-of-entry, which process visitors' entries
    - Port-of-exit, which process visitors' exits
    - Immigration, which process visitors' extension of stay
    - National security, which has to provide instructions to other departments concerning the security of the border
    - With this tight connectedness and the identification of visitors the country government can significantly enhance its processing of travelers for better security and country image.

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OTHER BUSINESS ITEM - NOT NOTICED ON THE AGENDA – FOR INFORMATION ONLY

IMPLEMENTATION OF SB 1159 (Vasconcellos)

The Disease Prevention Demonstration Project

The Disease Prevention Demonstration Project (DPDP)

SB 1159 (Vasconcellos)

Evaluation Advisory Panel Description and Roles

Summary:
The Governor recently signed new legislation has the potential to greatly enhance prevention activities that can reduce transmission of syringe-mediated blood-borne diseases such as HIV and hepatitis C (HCV). With the recent signing and enactment of Senate Bill 1159 (SB 1159, Vasconcellos), local cities and counties can now legally authorize the establishment of the Disease Prevention Demonstration Project (DPDP), allowing pharmacies to sell syringes without requiring a doctor's prescription. The new legislation stipulates that the California Department of Health Services (DHS) must convene an uncompensated Evaluation Advisory Panel and, in coordination with this panel, design and implement a comprehensive evaluation that will assess the impact that SB 1159 has on HIV and HCV risk behaviors as well as the health and well-being of surrounding communities and stakeholders.

Evaluation Advisory Panel Composition

SB 1159 requires that the panel include the following:

- Infectious disease control specialists
- California State Board of Pharmacy representative(s)
- Representative(s) of independent pharmacies
- Representative(s) of chain pharmacies
- Law enforcement representatives
    - Executives, such as police chiefs and sheriffs
    - Rank and file officers
- Specialist(s) in hazardous waste management from DHS
- Waste management industry representative(s)
- Local health officers

Focus of Pharmacy Access Evaluation
SB 1159 requires that DHS evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010.

The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

California, 2004

The Disease Prevention Demonstration Project (DPDP)

PURPOSE OF THE NEW PHARMACY ACCESS LEGISLATION

To prevent the spread of HIV, hepatitis, and other blood-borne diseases among injection drug users (IDUs), their sexual partners, and their children.

SUMMARY

Senate Bill (SB) 1159, subject to authorization by a county or city, creates the Disease Prevention Demonstration Project (DPDP), a collaboration between pharmacies and local and state health officials, and authorizes pharmacists in licensed pharmacies, who have registered with their local health department, to sell ten or fewer hypodermic needles or syringes for human use without a prescription. This provision sunsets on December 31, 2010. SB 1159 requires pharmacies that make such sales to undertake prescribed activities including offering safe syringe disposal programs to ensure that these hypodermic needles and syringes are disposed of in an appropriate manner, and providing written information or verbal counseling on how to access drug treatment and testing and treatment of human immunodeficiency virus (HIV) and hepatitis C virus (HCV). SB 1159 authorizes a person to possess up to ten hypodermic needles or syringes if acquired through an authorized source and deletes both the identity requirement and the requirement that a pharmacist keep detailed records of nonprescription sales of hypodermic needles and syringes. SB 1159 requires that the Department of Health Services (DHS) evaluate the effects of allowing the sale of hypodermic needles or syringes without a prescription, and submit a report to the Governor and Legislature by January 15, 2010.

WHAT DOES SB 1159 DO?

General Components:

- Establishes the DPDP, a collaboration between pharmacies and local and state health officials, to evaluate the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and HCV.

Pharmacy Components:

- Authorizes a licensed pharmacist, until December 31, 2010, to sell or furnish ten or fewer hypodermic needles or syringes to a person 18 years or older for human use without a prescription if the pharmacist works for a pharmacy that is registered with the local health department for DPDP.

- Requires participating pharmacies to:
    - 1) register with their local health department and certify that they will provide the purchaser with written information or verbal

counseling on all of the following: how to access drug treatment; how to access testing and treatment for HIV and HCV; and, how to safely dispose of sharps waste;
    - 2) store hypodermic needles and syringes so that they are available only to authorized personnel; and
    - 3) provide for the safe disposal of hypodermic needles and syringes through one or more of the following options: providing an on-site safe hypodermic needle and syringe collection and disposal program; furnishing or making available for purchase mail-back sharps disposal containers that meet state and federal standards; and furnishing or making available for purchase personal sharps disposal containers.

- Deletes the current requirement that a pharmacist keep detailed records of nonprescription sale of hypodermic needles and syringes and delete the requirement that a signature and address be obtained from the person to whom the needle or syringe was furnished.

IDU-Medical Patient Components:

- Allows a person who is 18 years or older to purchase ten or fewer hypodermic needles or syringes without a prescription at pharmacies that registered with a local DPDP

- Authorizes, from January 1, 2005 until December 31, 2010, a person to possess ten or fewer hypodermic needles or syringes if acquired through an authorized source.

- Makes it unlawful to discard or dispose a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school. SB 1159 would make a knowing violation of this prohibition a crime, punishable by a fine ($200-2,000), imprisonment (up to 6 months), or both.

- Exempts syringes that have been appropriately containerized for safe disposal from paraphernalia statutes, i.e., those syringes cannot be used as evidence of possession of drug paraphernalia. (A permanent change in law does not sunset in 2010.)

DHS Components:

- Requires DHS to convene an uncompensated advisory panel comprised of specialists, representatives, and stakeholders from the State, health, pharmacy, law enforcement, and waste management communities.

- Requires DHS, in conjunction with the advisory panel, to evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number

of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010. The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

- SB 1159 encourages DHS to seek funding from private and federal sources to pay for the evaluation.

Local Health Department Components:

- Require local health departments to:
  - 1) maintain a list of all pharmacies that have registered under DPDP;
  - 2) make available to pharmacies written information that may be provided or reproduced to be provided in writing or orally by the pharmacy to the customer at the time of furnishing or sale of nonprescription hypodermic needles or syringes. This information will include: how to access drug treatment; how to access testing and treatment for HIV and HCV; and how to safely dispose of sharps waste.

Pharmacy Access to Over-the-Counter Syringes in California

Thomas J. Stopka, MHS and Alessandra Ross, MPH

CCLHO Meeting

Oakland, California
February 17, 2005

SB 1159 (Vasconcellos)

- Signed by Governor on September 20, 2004
- Allows for establishment of the Disease Prevention Demonstration Project (DPDP)
  - Certified pharmacies can sell syringes OTC without a doctor's prescription until 12/31/2010
- Requires collaboration between pharmacies, LHJs, and DHS
  - Implementation
  - Evaluation

Disease Prevention Demonstration Project

- Opt-in oriented
- Must be authorized by:
  - County (Board of Supervisors) or
  - City (City Council)

Individuals everywhere in the state now can:

- Carry used syringes in a container and these syringes cannot be considered as illegal drug paraphernalia.
- There is no limit on the number of syringes that may be carried in a container.
- The type of container is not specified by the law (must meet state and federal standards)

Individuals in LHJs with a DPDP can:

- Purchase up to 10 syringes without a Rx if they are at least 18 years of age
- Legally possess up to 10 syringes if acquired from an authorized source

Local Health Jurisdictions (LHJs)

- Maintain a list of registered pharmacies for a local DPDP
- Make written information available to pharmacies to be shared with customers:
  - How to access drug Tx
  - How to access HIV and HCV C&T and Tx
  - How to safely dispose syringes

Participating pharmacies must:

- Register with LHJ and certify that will provide purchaser with written or verbal info on:
  - How to access drug Tx
  - How to access HIV and HCV C&T and Tx
  - How to safely dispose of syringes
- Store syringes so that only accessible to staff
- Provide for safe syringe disposal through:
  - On-site syringe disposal program
  - Furnishing or selling mail-back sharps containers, or
  - Furnishing or selling personal sharps containers

DHS

- Convene an uncompensated evaluation advisory committee including:
  - Infectious disease control specialists
  - State board of pharmacy reps
  - Independent and chain pharmacy owners
  - Law enforcement execs and officers
  - Waste management specialists
  - Local health officers

OA Evaluation Responsibilities

- Seek funding from private and federal sources for evaluation
  - Submitting grant to NIDA May 1, 2005
  - Other state and national agencies
- Conduct evaluation to monitor effects of the DPDP
  - Syringe sharing practices
  - Rates of disease infection
  - Needlestick injuries
  - Drug crime or other crime
  - Safe or unsafe discard
  - Rates of injection

Resources

- JAPhA Supplement: Pharmacy syringe sales and safe syringe disposal
  http://www.aphanet.org/JAPhA/suppl2_cdc.pdf
- Home generated sharps consolidation points
  - http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/homegenmw/HomeGenShConsolPtfeb04.pdf
- Syringe disposal website (CDC)
  - http://www.cdc.gov/needledisposal/

Resources

- Center for Health Improvement Website chipolicy.org (includes links to previously mentioned sites)

Ideas from the field…

- Syringe discard kiosks (Ottawa)
- Pharmacist peer education
- Outreach workers to meet pharmacists
- Fitpacks
- Program promotion/social marketing
- Partnership with diabetic associations
- Work with pharmacist associations
- Form community collaborations
- Be resourceful and creative…

Partners in Implementation

"In any city or county that authorizes non-prescription sale, Walgreens intends to encourage all of our pharmacies to participate…I expect that most…of our outlets will cooperate with local health departments to implement the life-saving strategies authorized by SB1159."

--Phil Burgess, Walgreens

DHS Office of AIDS (OA): Present and Future Activities

- Implementation support
  - Connecting people with resources
    - Others in the field doing the work
    - Templates
    - Research articles
  - Making contact with major pharmacy chains and statewide organizations and agencies
- Evaluation activities

Potential Roles

- CCLHO
- CA Board of Pharmacy
- CA Waste Management
- Others…:
  - SB 1159 Technical Assistance Conference?
  - Peer-to-peer technical support (Health Officer to Health Officer)

What's happening in your LHJ?

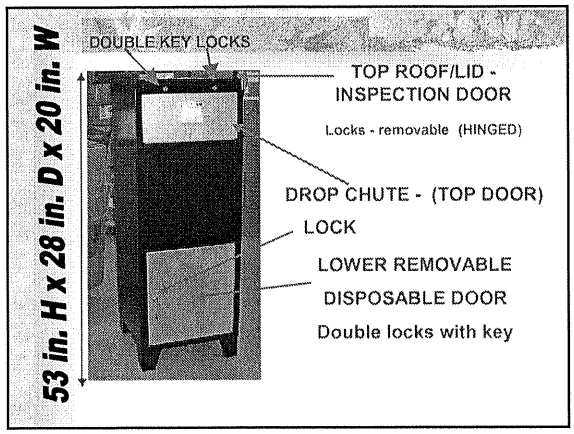
- Convening stakeholders?
- Education of lawmakers and policy leaders?
- Formalizing pharmacy registration?
- Ordinance language?

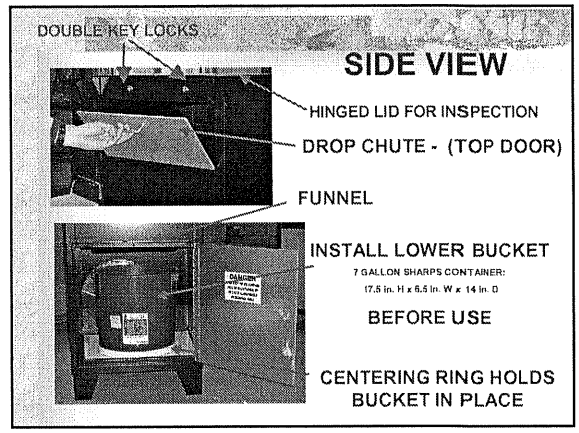
How can OA provide support?

- Fact sheets
- Communicate with pharmacy chains
- Pharmacy access website
- Provide other states' experiences
- Letter of support
- Pharmacy access resources

Safe Syringe Disposal Kiosks

- Used in New York, Seattle, New Mexico
- Contact Person in Ottawa:
  - Russ Salo:
    - Email: rsalo@burnsion.com
    - Phone: 800 653 1222





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